

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 2/9/2021 1:50:37 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr];
(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6)]; (b) (6)
Arvin, Ann [(b) (6) Beth Bell ((b) (6) [(b) (6)
(b) (6) Cavaleri Marco [(b) (6) (b) (6) mmdavis
[(b) (6) (b) (6) Greg Glenn [(b) (6)
(b) (6) Haynes, Barton [(b) (6) (b) (6) (b) (6)
Marks, Peter (FDA/CBER) [(b) (6) Mascola, John (NIH/VRC) [E] [(b) (6)
Messonnier, Nancy (CDC/DDID/NCIRD/OD) [(b) (6) Nelson Michael [(b) (6)
Offit, Paul [(b) (6) (b) (6) Seals, Jonathan (OS/ASPR/BARDA)
[(b) (6) (b) (6) (b) (6) Tal Zaks
[Tal. (b) (6)
CC: Tolman, Brett [(b) (6)]; (b) (6) Hopps, Markay [(b) (6)
Kozlowski, Mary (NIH/NCI) [C] [(b) (6) Johnson, Maureen (NIH/NCI) [E]
[(b) (6) (b) (6) Jeneffer Haynes [(b) (6)
(b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]
[(b) (6) .gov]; (b) (6) Isabel Ramsey [(b) (6) Parker,
Ashley (NIH/OD) [E] [(b) (6) Embry, Alan (NIH/NIAID) [E] [(b) (6) Erbeiding, Emily
(NIH/NIAID) [E] [(b) (6) Dieffenbach, Carl (NIH/NIAID) [E] [(b) (6) Qashu,
Felicia (NIH/OD) [E] [(b) (6) Culp, Michelle (NIH/OD) [E] [(b) (6) Gadbois, Ellen
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadbois]; Wholley, David (FNIH) [T]
[(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Menetski, Joseph (FNIH) [T]
[(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6)
James, Stephanie (FNIH) [T] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6)
Lumsden, Joanne (NIH/NCATS) [C] [(b) (6) Desrosiers, Betsy [(b) (6)
Eric Hughes [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Read, Sarah
(NIH/NIAID) [E] [(b) (6) Young, John [(b) (6) Paul Gillard
[(b) (6) François P Roman [(b) (6) Hamilton, Holli (OS/ASPR/BARDA)
[(b) (6) Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA)
[(b) (6) Kathleen Neuzil [(b) (6) Martin, Stacey
(CDC/DDID/NCEZID/DVBD) [(b) (6) McNamara, Lucy Alexandra (CDC/DDID/NCIRD/DBD) [(b) (6)];
Goldstein, Jason (CDC/DDID/NCEZID/DSR) [(b) (6) Schrag, Stephanie (CDC/DDID/NCIRD/DBD)
[(b) (6) Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [(b) (6) Lindsey, Nicole
(CDC/DDID/NCEZID/DVBD) [(b) (6) Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [(b) (6)];
Gonzalez, Nina [(b) (6) 'Wachtel, Jonathan' [(b) (6) Stratton, Benjamin
[(b) (6) Margaret Anderson [(b) (6) (b) (6)
(b) (6) Bethany Stokes [(b) (6) Kathleen Callahan
[(b) (6) Molloy, Delia (DPH) [(b) (6) Wood, Gretchen (NIH/OD) [E]
[(b) (6) Filip Dubovsky [(b) (6) Michael Watson (x)
[(b) (6) Jacqueline Miller [(b) (6) Antonio Lanzavecchia
[(b) (6) Arvin, Ann [(b) (6) Harris, Rebecca /SG [(b) (6)
Vivek Shinde [(b) (6) Cohen, Myron [(b) (6) Criffield, Robin R.
[(b) (6) Marovich, Mary (NIH/NIAID) [E] [(b) (6) FNIH
[(b) (6) Barton Haynes, M.D. [(b) (6) Michael, Nelson
[(b) (6) Gilbert PhD, Peter B [(b) (6) Bloom PhD, Jesse D
[(b) (6) (b) (6) Christopher Murray [(b) (6) pennym [(b) (6)
Alex Sigal (b) (6) Offit, Paul [(b) (6) Randy Hyer [(b) (6) Ho,
David D. (b) (6)

Subject: ACTIV Vaccines Working Group meeting
Location: <https://fnih.zoom.us/j/> (b) (6)
Start: 2/11/2021 4:30:00 PM

End: 2/11/2021 5:45:00 PM

Show Time As: Busy

Required Attendees: Santos, Michael (FNIH) [T]; (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6)
Arvin, Ann; Beth Bell (b) (6) (b) (6) Cavaleri Marco; (b) (6)
(b) (6) Emil (b) (6) Greg Glenn; (b) (6) Haynes,
Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];
Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6); Seals, Jonathan
(OS/ASPR/BARDA); Jim.Tart (b) (6) (b) (6) Tal Zaks
Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen
(NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)
(b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker,
Ashley (NIH/OD) [E]; Embry, Alan (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Dieffenbach, Carl (NIH/NIAID) [E];
Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T];
Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James,
Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Desrosiers, Betsy; Hughes,
Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; François P Roman;
Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Martin,
Stacey (CDC/DDID/NCEZID/DVBD); McNamara, Lucy Alexandra (CDC/DDID/NCIRD/DBD); Goldstein, Jason
(CDC/DDID/NCEZID/DSR); Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD);
Lindsey, Nicole (CDC/DDID/NCEZID/DVBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel,
Jonathan; Stratton, Benjamin; Anderson, Margaret; (b) (6)
(b) (6) Bethany Stokes; Kathleen Callahan; Molloy, Delia (DPH); Wood, Gretchen
(NIH/OD) [E]; Filip Dubovsky; Michael Watson (x); Jacqueline Miller; Antonio Lanzavecchia; Ann Arvin; Harris,
Rebecca /SG; Vivek Shinde; Cohen, Myron; Criffield, Robin R.; Marovich, Mary (NIH/NIAID) [E]; FNIH; Barton Haynes,
M.D.; Nelson Michael; Gilbert PhD, Peter B; Bloom PhD, Jesse D; t (b) (6); Christopher Murray; pennym;
Alex Sigal; Ho, David D.; Offit, Paul; Randy Hyer

Topic: ACTIV Vaccines Working Group meeting

Time: Feb 11, 2021 11:30 AM Eastern Time (US and Canada)

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Find your local number: [https://fnih.zoom/j/\(b\)\(6\)](https://fnih.zoom/j/(b)(6))

From: (b) (6) [(b) (6)]
Sent: 6/10/2020 9:08:02 AM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
Subject: Fwd: Agenda and materials for the Protective Immune Responses Sub-Group meeting
Attachments: image001.jpg; ATT00001.htm; image002.jpg; ATT00002.htm; image003.jpg; ATT00003.htm; image004.jpg; ATT00004.htm; Assay WG Tracker _ Updated 6-4.xlsx; ATT00005.htm

Forwarding the information for the vaccines subgroup meeting taking place at 2:30pm today "inter-comparability of immunogenicity assays and centralized labs" and follow up conversations with Janet next week on assay development by vaccine developers — FYI.

Seems there are already POCs for NIAID.

Best,
Ashley

Begin forwarded message:

From: "Santos, Michael (FNIH) [T]" <m (b) (6)>
Date: June 9, 2020 at 10:59:53 PM EDT
To: (b) (6)
(b) (6)
(b) (6) "Gruber, Marion (FDA/CBER)"
(b) (6) "Marks, Peter (FDA/CBER)" (b) (6)
(b) (6) "Arvin, Ann"
< (b) (6) Nelson Michael (b) (6) "Bett, Andrew J"
(b) (6) "Gilbert PhD, Peter B" (b) (6) "Kathleen Neuzil"
(b) (6) "Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA)"
>, "Thornburg, Natalie (CDC/DDID/NCIRD/DVD)" < (b) (6)
Greg Glenn (b) (6) >, Cavaleri Marco (b) (6) "Kelly, Beth"
(b) (6)
Cc: "Tolman, Brett" (b) (6)
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(b) (6) Jeneffer Haynes (b) (6)
"Menetski, Joseph (FNIH) [T]" (b) (6) "Alvarez, Rosa Maria"
"Wholley, David (FNIH) [T]" < (b) (6) "Parker, Ashley (NIH/OD) [E]"
(b) (6) Brian Rosen (b) (6) Cheryl Keech (b) (6) >
Subject: Agenda and materials for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting at 2:30pm ET (11:30am PT / 6:30pm CEST).

Last week we were fortunate to have Marco Cavaleri present and lead a discussion on EMA regulatory pathways. Development of a table of those pathways analogous to the table developed for FDA pathways is underway.

At this meeting we will return to the topics from two weeks ago: (1) reaching out to collect information on potential signals of human immunity and (2) inter-comparability of immunogenicity assays and centralized labs.

Since that meeting Ann and Mark Davis discussed the first topic, and reached out to Dan Rotrosen (Director of the Division of Allergy, Immunology, and Transplantation at NIAID). He is unfortunately unable to join this meeting, but we will discuss the categories of information we would like to collect and the potential process for doing so.

On the second topic, we reached out to Janet Lathey (NIAID) and Ashley Smith (BARDA), who co-lead a USG working group on assay development. They kindly provided the attached draft list of assays under development through USG mechanisms. Janet will join our meeting next week to discuss the assays and engagement by vaccine developers with the labs running them.

Please let us know if you have any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Wednesday, June 3, 2020 11:30 PM
Subject: Notes from yesterday's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting, and particular thanks to Marco for the excellent presentation and discussion.

Meeting notes are attached, with the meeting materials are embedded. The key action item is developing a table of EMA pathways analogous to the one that we previously developed with Marion's input and review for FDA pathways.

Please reach out with any additions or edits to the notes, questions, or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Monday, June 1, 2020 1:04 PM
Subject: Agenda and materials for the Protective Immune Responses Sub-Group meeting tomorrow (Tuesday)

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting tomorrow (Tuesday) at 8am ET (5am PT / 2pm CEST). We are very sorry for the extremely early start PT.

The main agenda item is to discuss EMA and member state regulatory pathways to vaccine use and approval. Marco will lead the discussion. He previously shared a set of presentation slides (re-attached here). We are also re-attaching the table on FDA pathways that we circulated previously.

Please let us know if you have any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Thursday, May 28, 2020 12:57 PM
Subject: Notes and next steps from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting. Notes are attached.

There were two key areas for next steps that we identified in the meeting:

- Potential signals of human immunity:
 - Develop specifics of what we are looking for from immunology research
 - Ask the WG and other contacts for suggestions of researchers/organizations worth reaching out to
 - Reach out and collect information and contacts to engage with the WG (in presentations or other formats)
- Inter-comparability of immunogenicity assays / centralized labs
 - Reach out to NIAID to learn more about planned centralized lab capabilities and timing

Ann kindly followed up with an initial set of recommendations for the first area. We'll be following up to develop the list of information that we'd like to gather and to discuss how to prioritize whom we reach out to. We'll reach out to NIAID and report back on the second area.

We think these topics will form the basis for future discussions, but we are also trying to schedule a meeting for a time when we can have a discussion about the EMA regulatory pathways with Marco, to complement the conversations we have had on FDA pathways. We hope to have an invite for that out soon.

As always, please reach out with any additional input on the notes, questions, or suggestions for future directions for this group.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 11:42 PM
Subject: Agenda for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to today's (Wednesday) meeting, at 9am ET (6am PT / 3pm CEST).

Since our last meeting, Marco kindly shared the attached document on EMA and member state regulatory pathways for vaccine use and approval. Unfortunately Marco won't be able to join this meeting, but has offered to discuss the EMA pathways at a future meeting.

Our recent meetings have focused primarily on understanding regulatory pathways for vaccine use and approval, and the types of evidence that factor into regulatory decisions for different pathways, with two presentations on upcoming sources of evidence (NIAID NHP challenge studies using sera/IgG/mAbs and CDC immunological studies). A key goal of this group is to facilitate vaccine developers to generate evidence that can support evaluation of vaccine efficacy. For today's meeting, we plan to discuss the different categories of evidence and identify priorities for ACTIV to engage to be supportive.

We look forward to the discussion. If you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 12:19 AM
Subject: Notes from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached notes and materials from our meeting last week. Thanks again to Donna and Natalie for presenting, and as always to Marion for her contributions to the regulatory pathways during the meeting and subsequently.

We will be in touch again soon regarding this week's meeting. Feel free to reach out any time with questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 19, 2020 8:56 AM
Subject: Agenda and Materials for today's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached two documents for today's Protective Immune Responses Sub-Group meeting (2pm ET / 11am PT / 8pm CEST):

- An updated table of pathways to vaccine use
- Notes from the last Sub-Group meeting (with my apologies for the delay)

For today's meeting, the agenda items are:

- Discussion of the updated pathways table and next steps
- An overview of the CDC's serology activities by Natalie

We're looking forward to the discussion today. As always, if you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health

(b) (6) | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

From: Menetski, Joseph (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/11/2020 10:53:07 PM
To: (b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas /US
(b) (6) Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Diamond, Michael [(b) (6) Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6) Prabhavathi Fernandes [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D (b) (6); Dave Frankowski (b) (6) Louise Pitt (b) (6) (b) (6)

Subject: RE: ACTIV Preclinical working group (Friday meeting)

Attachments: 2020-05-08_Preclinical_WG_Summary_D3.docx; Therapeutic information request form d1.docx; ACTIV Partnership Leadership Team Meeting 20200506 FINAL.pdf; 2020-05-06_ACTIV_Leadership_Group_Meeting_Summary FINAL.pdf

Dear Preclinical Working group members and invitees,

Attached please find the minutes from Friday's meeting for your review. If you find any mistakes, please let me know.

As part of the action items, Michael Diamond and I we tasked with drafting a 1-2 page document with information for prioritization of preclinical therapies for the expert panel to use. I have attached a first draft of what that, and have formatted it in a way that we might be able to use to collect the information from potential therapy sponsors. This actually contains info from animal (and can have anything about clinical data if repurposing). Your thoughts and suggestions about that will be helpful also.

Finally, I am attaching the slides and the minutes from the Leadership Team Meeting on 5/6/2020 for your review.

Best regards,
Joe

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:48 PM

To: (b) (6) (b) (6) (b) (6) Menetski, Joseph (FNIH) [T];

(b) (6) (b) (6) (b) (6) (b) (6)

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(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Anderson, James (NIH/OD) [E]

Cc: Diamond, Michael; Florence, Clint (NIH/NIAID) [E]; Wholley, David (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Lowy, Douglas (NIH/NCI) [E]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Louise Pitt (b) (6)

Subject: ACTIV Preclinical working group (Friday meeting)

When: Friday, May 8, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom>. (b) (6)

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Password: (b) (6)

Find your local number: <https://fnih.zoom>, (b) (6)

From: Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 8/14/2020 4:37:33 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: FW: ACTIV website updates per EC slides/meeting today

FYI below. Ellen raised the need to revise the website since two of the WG aren't meeting anymore. I told her we are working on revisions.

I'm guessing it is fine to wait to address this until all the changes are ready (so it doesn't have to be updated twice) but let me know if you think otherwise.

Thanks!
Lauren

From: Brodd, Lauren (NIH/OD) [E]
Sent: Friday, August 14, 2020 12:35 PM
To: Gadbois, Ellen (NIH/OD) [E] <(b) (6)>
Subject: RE: ACTIV website updates per EC slides/meeting today

Hi Ellen,

Thanks for flagging! Ashley and I have been working with Renate and her team to revise the website to provide more detailed information about each of the working groups. In the updated version, we include language about the clinical trial capacity group being finished as of 7/31 and the vaccines group now only meeting on an ad hoc basis. Not sure the exact timeline (FNIH is currently reviewing the drafts) but those groups will be addressed when the updated version goes live.

Thanks,
Lauren

From: Gadbois, Ellen (NIH/OD) [E] <(b) (6)>
Sent: Friday, August 14, 2020 12:18 PM
To: Brodd, Lauren (NIH/OD) [E] <(b) (6)>
Subject: ACTIV website updates per EC slides/meeting today
Importance: High

You may want to revise how the working groups are listed on the website since clinical trials capacity is done, and vaccine is suspended (may be reconvened if needed)—see slides.

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Thursday, August 13, 2020 10:20 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>; Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)>; Dolsten, Mikael <(b) (6)>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>; Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)>; Marks, Peter (FDA/CBER) <(b) (6)>; Pao, William <(b) (6)>; Plump, Andrew <(b) (6)>; Stoffels, Paul <(b) (6)>; Woodcock, Janet (FDA/CDER) <(b) (6)>; Colvis, Christine (NIH/NCATS) [E] <(b) (6)>; Desrosiers, Betsy <(b) (6)>; Eric Hughes <(b) (6)>; Jansen, Kathrin <(b) (6)>; Kurilla, Michael (NIH/NCATS) [E] <(b) (6)>; Lowy, Douglas (NCI) <(b) (6)>; Read, Sarah (NIH/NIAID) [E] <(b) (6)>

Young, John < (b) (6) Wholley, David (FNIH) [T] < (b) (6)
Cc: Anderson, James (NIH/OD) [E] < (b) (6) Austin, Christopher (NIH/NCATS) [E]
(b) (6) ; Burklow, John (NIH/OD) [E] (b) (6) Castillejos, Carlos (b) (6)
Culp, Michelle (NIH/OD) [E] (b) (6) FNIH Central Account (b) (6) ; Freire, Maria
(FNIH) [T] (b) (6) >; Gadbois, Ellen (NIH/OD) [E] (b) (6) ; Hallett, Adrienne (NIH/OD) [E]
(b) (6) >; Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Myles, Renate (NIH/OD) [E]
(b) (6) ; Parker, Ashley (NIH/OD) [E] (b) (6) >; Tabak, Lawrence (NIH/OD) [E]
(b) (6) >; Wolinetz, Carrie (NIH/OD) [E] < (b) (6) >; Melencio, Cheryl (FNIH) [T]
(b) (6) >; Adam, Stacey (FNIH) [T] (b) (6) ; Alvarez, Rosa (b) (6) >;
Anderson, Margaret < (b) (6) >; Chen, Helen (b) (6) Elsaid, Olivia
(b) (6) >; Gonzalez, Nina (b) (6) >; Hawk, Harrison (b) (6) >;
Menetski, Joseph (FNIH) [T] (b) (6) >; Santos, Michael (FNIH) [T] (b) (6) >; Stratton, Benjamin
< (b) (6) >; Tolman, Brett < (b) (6) >; Tountas, Karen (FNIH) [T] < (b) (6)
Wachtel, Jonathan < (b) (6)

Subject: Materials for August 14 ACTIV Executive Committee Teleconference

Importance: High

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from **12:00 – 1:00 PM Eastern U.S. time** tomorrow, Friday, August 14. I have also attached notes from our July 29 Leadership Team meeting as well as our last EC meeting on July 15. As you know we will be hearing from two Working Groups instead of four, **so the co-chairs have decided to make this call as well as future EC and LT calls going forward 60 minutes in length instead of 90 minutes.**

The Zoom information is:

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Please let Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/8/2020 3:59:15 AM
To: Jim Neaton [(b) (6)]; Jens Lundgren [(b) (6)]; Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Karen Lynn Price [(b) (6)]; LaVange, Lisa M [(b) (6)]; Sandeep Menon [(b) (6)]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [(b) (6)]; William Erhardt [(b) (6)]; (b) (6) [(b) (6)]; Gelijns, Annetine [(b) (6)]; Moskowitz, Alan [(b) (6)]; Ab Babiker [(b) (6)]; Cavan, Reilly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=995fe0f1a53c443a832f96f003f0f2c5-cavanr.bios]; Phillips, Andrew [(b) (6)]; [(b) (6)]; Birgit Grund [(b) (6)]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f2b26b051964d9da6868e53c9cc6c49-jim.ccbr.um]; Joe Koopmeiners [(b) (6)]; David Vock [(b) (6)]; Thomas Murray [(b) (6)]; Max Parmar [(b) (6)]; Mark Polizzotto [(b) (6)]; Ginny Kan [(b) (6)]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Baker, Jason [(b) (6)]; Roger Paredes [(b) (6)]; (b) (6) [(b) (6)]; (b) (6) [(b) (6)]; (b) (6) [(b) (6)]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey], (b) (6) [(b) (6)]; Ajay Nirula [(b) (6)]; Paul Klekotka [(b) (6)];
CC: Demarcus [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chen, Helen Q. [(b) (6)]; Eron, Joseph J Jr [(b) (6)]; Chew, Kara M.D. [(b) (6)]; Daar, Eric [(b) (6)]; Bagiella, Emilia [(b) (6)]
Subject: ACTIV-3 Writing Team Meeting
Attachments: ACTIV_TX-Clinical_ACTIV-3 Writing Team Meeting Agenda_20200608.pdf
Location: <https://fnih.zoom.us/> (b) (6)
Start: 6/8/2020 3:00:00 PM
End: 6/8/2020 4:00:00 PM
Show Time As: Tentative

Required Attendees: Jim Neaton; Jens Lundgren; Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA); Patterson, Amy (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Reineck, Lora (NIH/NHLBI) [E]; Judy Currier; Karen Lynn Price; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; William Erhardt; (b) (6) Gelijs, Annetine; Moskowitz, Alan; Ab Babiker; Cavan, Reilly; Phillips, Andrew (b) (6) Birgit Grund; Neaton, Jim; Joe Koopmeiners; David Vock; Thomas Murray; Max Parmar; Mark Polizzotto; Ginny Kan; Lane, Cliff (NIH/NIAID) [E]; Baker, Jason; Roger Paredes; (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) Rosenberg, Yves (NIH/NHLBI) [E]; (b) (6)
(b) (6) Ajay Nirula; Paul Klekotka

Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Parker, Ashley (NIH/OD) [E]; Chen, Helen Q.; Eron, Joseph J Jr; Chew, Kara M.D.; Daar, Eric; Bagiella, Emilia

Monday, June 8, 2020 – 11-12pm ET

Dear ACTIV-3 Writing Team,

Please find attached the agenda for tomorrow's call. I will distribute any other materials for the meeting in the morning.

Thanks,

Stacey

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/20/2020 1:26:57 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Stratton, Benjamin [(b) (6)]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]
Subject: FW: Clinical Trial Capacity WG - meeting #1 summary

Can we please send an invitation to Robert Johnson to attend the Wednesday ACTIV leadership group call? He will likely be replacing Rick Bright on that call, but we won't know for sure until Francis Collins has had a few more conversations.

From: Johnson, Robert (OS/ASPR/BARDA) < (b) (6) >
Sent: Monday, April 20, 2020 7:04 AM
To: Wholley, David (FNIH) [T] < (b) (6) >
Cc: Tountas, Karen (FNIH) [T] < (b) (6) > Walker, Robert (OS/ASPR/BARDA) < (b) (6) >
Subject: RE: Clinical Trial Capacity WG - meeting #1 summary

David,

Hi and thanks for the follow-up. your assessment aligns with mine-so it's okay if we remove Jim from the list of participants for this WG?

Thanks.

Robert

Robert Johnson, Ph.D.
Director, Influenza and Emerging Infectious Diseases Division
Biomedical Advanced Research and Development Authority
BARDA
Assistant Secretary for Preparedness and Response ASPR
Department of Health and Human Services
330 Independence Avenue, S.W. Room 640 G
Washington, D.C. 20201
Office: (b) (6)
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email: (b) (6) v

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From: Wholley, David (FNIH) [T] (b) (6) >
Sent: Sunday, April 19, 2020 7:12 AM
To: Johnson, Robert (OS/ASPR/BARDA) (b) (6)
Cc: Tountas, Karen (FNIH) [T] (b) (6)
Subject: FW: Clinical Trial Capacity WG - meeting #1 summary

Hi Robert, Karen Tountas forwarded me your note below. Francis Collins asked Rick Bright for names for three of the groups—Clinical TX, Preclinical TX, and Vaccines. There was no request for a BARDA representative for the Clinical Trial Capacity group that I'm aware of, although if BARDA wanted to add one I'm sure there would be no objection.
David Wholley

From: Johnson, Robert (OS/ASPR/BARDA) (b) (6)
Sent: Sunday, April 19, 2020 6:55 AM
To: Tountas, Karen (FNIH) [T] (b) (6)
Cc: Walker, Robert (OS/ASPR/BARDA) <(b) (6)>; King, James (OS/ASPR/BARDA) (b) (6) >; Johnson, Robert (OS/ASPR/BARDA) (b) (6) >
Subject: FW: Clinical Trial Capacity WG - meeting #1 summary

Karen,

Good morning. My name is Robert Johnson and I serve as the IMT manager for the COVID-19 response in BARDA. I'm trying to sort something out and hope you can help. Last weekend BARDA was asked to provide names of individuals to sit on three of the four PPP WGs. We were not asked to provide a name for the fourth working group, Clinical Trial Capacity, so we did not put one forth. I am not sure how Dr. King's name was added to the roster. Can you please clarify if BARDA is being requested to add someone to this WG? If so, we'll circle back with a name.

Thank you.

Robert

Robert Johnson, Ph.D.
Director, Influenza and Emerging Infectious Diseases Division
Biomedical Advanced Research and Development Authority
BARDA
Assistant Secretary for Preparedness and Response ASPR
Department of Health and Human Services
330 Independence Avenue, S.W. Room 640 G
Washington, D.C. 20201
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From: King, James (OS/ASPR/BARDA) <(b) (6)>
Sent: Friday, April 17, 2020 8:21 AM
To: Johnson, Robert (OS/ASPR/BARDA) (b) (6)
Subject: FW: Clinical Trial Capacity WG - meeting #1 summary

I will send this to you and I will call.

Jim King

From: Tountas, Karen (FNIH) [T] (b) (6)
Sent: Thursday, April 16, 2020 11:46 AM
To: Bascles, Lionel (b) (6) >; Cohen, Myron (b) (6) >; Corey, Larry <(b) (6)>; Desrosiers, Betsy (b) (6) >; Dickens, Jim (NIH/NCATS) [C] (b) (6) >; Doroshow, James (NIH/NCI) [E] (b) (6) >; Goff, David (NIH/NHLBI) [E] <(b) (6)>; King, James (OS/ASPR/BARDA) (b) (6) >; Kurilla, Michael (NIH/NIAID) [E] (b) (6) >; Nayak, Seema (NIH/NIAID) [E] (b) (6) >; Parker, Ashley (NIH/NCI) [F] <(b) (6)>; Payton, Manizhe (NIH/NIAID) [E] (b) (6) >; Resnansky, Laura <(b) (6)>; Srinivasan, Badhri (b) (6) >; Stein, Peter (FDA/CDER) (b) (6) >; Vincent, Mike (b) (6) >; Woodcock, Janet (FDA/CDER) (b) (6) >
Cc: Colvis, Christine (NIH/NCATS) [E] (b) (6) >; Hughes, Eric (b) (6) >; Jansen, Kathrin (b) (6) >; Lowy, Douglas (NCI) (b) (6) >; Read, Sarah (NIH/NIAID) [E] (b) (6) >; Young, John (b) (6) >; Criffield, Robin (b) (6) >; Hamilton, Nancy (b) (6) >; Melencio, Cheryl (FNIH) [T] (b) (6) >; Minnich, Beth (b) (6) >; Katz, Rebecca (NIH/NCATS) [E] (b) (6) >; Thomas, Ashley (FDA/CDER) <(b) (6)>; Adam, Stacey (FNIH) [T] <(b) (6)>; Anderson, Margaret (b) (6) >; Carluccio, Dana <(b) (6)>; Melencio, Cheryl (FNIH) [T] (b) (6) >; Gonzalez, Nina (b) (6) >; Heaton, Penny (b) (6) >; James, Stephanie (FNIH) [T] <(b) (6)>; Li, Rose (b) (6) >; Menetski, Joseph (FNIH) [T] <(b) (6)>; Santos, Michael (FNIH) [T] <(b) (6)>; Tuveson, Nancy <(b) (6)>; Wholley, David (FNIH) [T] (b) (6) >; Wachtel, Jonathan <(b) (6)>
Subject: RE: Clinical Trial Capacity WG - meeting #1 summary

Apologies, attached is a cleaner version.
Karen

From: Tountas, Karen (FNIH) [T]
Sent: Thursday, April 16, 2020 6:10 AM
To: Bascles, Lionel (b) (6) >; Cohen, Myron (b) (6) >; Corey, Larry (b) (6) >; Desrosiers, Betsy (b) (6) >; Dickens, Jim (NIH/NCATS) [C] (b) (6) >; Doroshow, James (NIH/NCI) [E] (b) (6) >; Goff, David (NIH/NHLBI) [E] (b) (6) >; King, James <(b) (6)>; Kurilla, Mike (b) (6) >; Nayak, Seema (NIH/NIAID) [E] (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) >; Payton, Manizhe (b) (6) >; Resnansky, Laura <(b) (6)>; Srinivasan, Badhri (b) (6) >; Stein, Peter (FDA/CDER) <(b) (6)>; Vincent, Mike <(b) (6)>

< (b) (6) Woodcock, Janet (FDA/CDER) < (b) (6)
Cc: Colvis, Christine (NIH/NCATS) [E] < (b) (6) >; Hughes, Eric (b) (6) >; Jansen, Kathrin (b) (6) >; Lowy, Douglas (NCI) (b) (6) >; Read, Sarah (NIH/NIAID) [E] (b) (6) >; Young, John (b) (6) >; Criffield, Robin (b) (6) Hamilton, Nancy (b) (6) >; Melencio, Cheryl (FNIH) [T] (b) (6) >; Minnich, Beth (b) (6) >; Rebecca (NIH/NCATS) Katz [E] (b) (6) >; Thomas, Ashley (FDA/CDER) (b) (6) >; Adam, Stacey (FNIH) [T] (b) (6) >; Anderson, Margaret < (b) (6) >; Carluccio, Dana (b) (6) >; Cheryl (FNIH) Melencio [T] (b) (6) >; Gonzalez, Nina (b) (6) >; Heaton, Penny (b) (6) >; James, Stephanie (b) (6) >; Li, Rose (b) (6) >; Menetski, Joseph (FNIH) [T] (b) (6) >; Santos, Michael (FNIH) (b) (6) >; Tuveson, Nancy <Nancy. (b) (6) >; Wholley, David (FNIH) [T] (b) (6) >; Wachtel, Jonathan < (b) (6) >

Subject: Clinical Trial Capacity WG - meeting #1 summary

Dear Clinical Trial Capacity Working Group colleagues,

Attached is a summary of meeting #1 of the Clinical Trial Capacity Working Group. It was a very good start to this effort; thank you to everyone for participating in this important initial discussion.

Looking forward to forming the subgroups and initiating detailed activities.

Karen

Karen H. Tountas, PhD

Scientific Program Manager

Foundation for the National Institutes of Health

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Sent: 4/30/2020 1:44:14 PM
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CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Stratton, Benjamin [(b) (6)]
Subject: RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Hi Sam,

I think you are correct and we can discuss more today and tomorrow. I am currently trying to figure out what the outreach procedure should be, but I agree it likely needs to sooner rather than later.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer
Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

From: Bozzette, Sam (NIH/NCATS) [E] <(b) (6)>

Sent: Thursday, April 30, 2020 9:19 AM

To: Adam, Stacey (FNIH) [T] <(b) (6)> Butterson, Joan <(b) (6)> Collins, Sylva
(FDA/CDER) <(b) (6)> Judy Currier <(b) (6)> De Claro, R. Angelo (FDA/CDER)
<(b) (6)> Mark Eisner <(b) (6)> Keith Gottesdiener
<(b) (6)> Eric Hughes <(b) (6)> LaVange, Lisa M <(b) (6)>
Elliott Levy <(b) (6)> Sandeep Menon <(b) (6)> Amanda Peppercorn
<(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah
(NIH/NIAID) [E] <(b) (6)> Amanda Peppercorn <(b) (6)> Price, Dionne
(FDA/CDER) <(b) (6)> Rubin, Daniel B. (FDA/CDER) <(b) (6)> Shen, Yuan Li
(FDA/CDER) <(b) (6)> Farley, John (FDA/CDER) <(b) (6)> Goff, David (NIH/NHLBI)
[E] <(b) (6)> Vincent, Michael <(b) (6)>
Cc: Mary Biggs <(b) (6)> Demarcus <(b) (6)> Macone, Erin <(b) (6)>
Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan <(b) (6)> Elizabeth Kim
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<(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T]
<(b) (6)> Wung, Peter /US <(b) (6)> Qashu, Felicia (NIH/OD) [E]
<(b) (6)> Stratton, Benjamin <(b) (6)>

Subject: Re: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Good morning all:

It would seem that our active control arm had been identified. Should we get in the queue with Gilead sooner rather than later - or have we already reached out to them?

S

From: "Adam, Stacey (FNIH) [T]" <(b) (6)>

Date: Thursday, April 23, 2020 at 8:31:00 PM

To: "Bozzette, Sam (NIH/NCATS) [E]" <(b) (6)> "Butterson, Joan" <(b) (6)>
"Collins, Sylva (FDA/CDER)" <(b) (6)> "Judy Currier" <(b) (6)> "De Claro, R.
Angelo (FDA/CDER)" <(b) (6)> "Mark Eisner" <(b) (6)> "Keith Gottesdiener"
<(b) (6)> "Eric Hughes" <(b) (6)> "LaVange, Lisa M"
<(b) (6)> "Elliott Levy" <(b) (6)> "Sandeep Menon" <(b) (6)>
"Amanda Peppercorn" <(b) (6)> "Proschan, Michael (NIH/NIAID) [E]"
<(b) (6)> , "Read, Sarah (NIH/NIAID) [E]" <(b) (6)> , "Amanda Peppercorn"
<(b) (6)> , "Price, Dionne (FDA/CDER)" <(b) (6)> "Rubin, Daniel B.
(FDA/CDER)" <(b) (6)> "Shen, Yuan Li (FDA/CDER)" <(b) (6)> "Farley, John
(FDA/CDER)" <(b) (6)> , "Goff, David (NIH/NHLBI) [E]" <(b) (6)> "Vincent, Michael"
<(b) (6)>
Cc: "Mary Biggs" <(b) (6)> "Demarcus" <(b) (6)> "Macone, Erin"
<(b) (6)> , "Tountas, Karen (FNIH) [T]" <(b) (6)> , "Wachtel, Jonathan"
<(b) (6)> , "Elizabeth Kim" <(b) (6)> , "Parker, Ashley (NIH/OD) [E]"
<(b) (6)> , "Butcher, Tina" <(b) (6)> "Wholley, David (FNIH) [T]"
<(b) (6)> "Melencio, Cheryl (FNIH) [T]" <(b) (6)> , "Wung, Peter /US"
<(b) (6)> , "Qashu, Felicia (NIH/OD) [E]" <(b) (6)> , "Stratton, Benjamin"

(b) (6)

Subject: RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for tomorrow's meeting.

1. Agenda
2. Slides for discussion updated with the decisions from today
3. A useful resource about current standard clinical treatment guidelines from the front lines for COVID. This may be a useful resource in selecting how to do minimal data collection and trying to understand SOC.

Please let me know if you have questions or other things you think would be helpful for the group to review.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

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[(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative
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(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative
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DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6)
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CC: Gonzalez, Nina [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange
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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group

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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
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 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Tolman, Brett
 [(b) (6) Alvarez, Rosa [(b) (6) Stratton, Benjamin [(b) (6)
 Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B.
 (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Chen, Helen Q.
 [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Elsaid, Olivia
 [(b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acb5fd03bafd32930-walkerpl]; Margaret Anderson
 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Gonzalez, Nina
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Colvis,
 Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
 [(b) (6) Jansen, Kathrin [(b) (6)]; Kurilla, Michael (NIH/NCATS) [E]
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 (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6)
 Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T]
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 [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Dana Carluccio
 [(b) (6) Rose Li Central Account [(b) (6) Lucas Smalldon
 [(b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; (b) (6) Mollica, Linda /US
 (b) (6) ; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20200916.pdf

Start: 9/17/2020 5:00:00 PM
End: 9/17/2020 6:00:00 PM

Recurrence: (none)

Required Attendees: Garner, Carl; Mellors, John; Levy, Elliot; Menon, Sandeep; Sizemore, Christine (NIH/FIC) [E]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6)

Optional Attendees: Anderson, Margaret; Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes

Stacey Adam is inviting you to a scheduled Zoom meeting.

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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 5/8/2020 4:44:09 PM
To: Bascles, Lionel [(b) (6)] Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6)] Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [(b) (6)] Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Garner, Carlos [(b) (6)] Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Resnansky, Laura [(b) (6)] Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [(b) (6)] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [(b) (6)] Wachtel, Jonathan [(b) (6)]
CC: Criffield, Robin [(b) (6)] Hamilton, Nancy [(b) (6)] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [(b) (6)]; Mueller-Reichenstein, Petra [(b) (6)] Quadros, Nora [(b) (6)] Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [(b) (6)] Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6)] James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6)] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [(b) (6)] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6)] Jansen, Kathrin [(b) (6)] Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)]

From: Read, Sarah (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=527B160038004A199AE6E0BAC2226099-READSA]
Sent: 9/10/2020 12:42:44 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: Materials for September 9 ACTIV Executive Committee Teleconference

Ok, I think the option of accessing pooled event rates in order to re-assess sample size is an option if the demographic changes could lead to significant changes in endpoint accumulation. Additionally, each of the teams receives regular reports from the Predictive Analytics Working Group of HHS Protect which show current and predicted incidence as well as demographics (age, race), hospitalization rates, etc at each of the trial sites. If a major shift in demographics is predicted, teams could choose to add more sites in different locations to address any imbalance.

Sarah

From: Wholley, David (FNIH) [T] <(b) (6)>
Sent: Wednesday, September 9, 2020 5:49 PM
To: Read, Sarah (NIH/NIAID) [E] <(b) (6)> Eric Hughes <(b) (6)>
Cc: Adam, Stacey (FNIH) [T] <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)>
Subject: RE: Materials for September 9 ACTIV Executive Committee Teleconference

The way I read this, he is asking in an open-ended way IF we see/know of/anticipate any shift in demographics, and how we are thinking of dealing with it. I did not read this as saying he knows there is a shift going on.

From: Read, Sarah (NIH/NIAID) [E] (b) (6)
Sent: Wednesday, September 9, 2020 3:59 PM
To: Wholley, David (FNIH) [T] (b) (6) Eric Hughes (b) (6) >
Cc: Adam, Stacey (FNIH) [T] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6) >
Subject: RE: Materials for September 9 ACTIV Executive Committee Teleconference

Thanks David. I'm not sure which shift in demographics he is referring to...perhaps toward younger patients testing positive. If so, this could affect the rates of endpoint accumulation across the trials since most were designed with assumptions based on where the pandemic was a couple of months ago. Protocol teams could work with their DSMBs to access pooled event rates at a certain point in order to perform sample size re-estimation. ACTIV1 has this written into the protocol...I'm not sure if the others do but could find out.

Do others think this is the question William is asking?? Or is there some other demographic shift going on. David, perhaps you could clarify with him?

Sarah

From: Wholley, David (FNIH) [T] (b) (6)
Sent: Wednesday, September 9, 2020 3:38 PM
To: Read, Sarah (NIH/NIAID) [E] (b) (6) >; Eric Hughes (b) (6)

Cc: Adam, Stacey (FNIH) [T] < (b) (6) >; Collins, Francis (NIH/OD) [E] (b) (6)

Subject: FW: Materials for September 9 ACTIV Executive Committee Teleconference

Dear Sarah and Eric:

Please see below another good question from William Pao received just now. Can you please advise on how I should answer this, and let me know if there are others with whom I should consult on the answer—happy to include Amy Patterson, etc. and round up a response. Thanks

From: Pao, William (b) (6) >

Sent: Wednesday, September 9, 2020 3:33 PM

To: Wholley, David (FNIH) [T] (b) (6)

Subject: RE: Materials for September 9 ACTIV Executive Committee Teleconference

Hi David,

I did have another question – are we seeing a shift in the demographics of the patients and how will that impact the ACTIV trials?

Best,

William

From: Melencio, Cheryl (FNIH) [T] (b) (6) > **On Behalf Of** Wholley, David (FNIH) [T]

Sent: Wednesday, September 9, 2020 2:53 PM

To: Collins, Francis (NIH/OD) [E] (b) (6); Disbrow, Gary (OS/ASPR/BARDA) (b) (6) >; Dolsten, Mikael (b) (6) >; Fauci, Anthony (NIH/NIAID) [E] < (b) (6) >; Gibbons, Gary (NIH/NHLBI) [E] < (b) (6) >; Marks, Peter (FDA/CBER) < (b) (6) >; Pao, William (b) (6) >; Plump, Andrew (b) (6) >; Stoffels, Paul (b) (6) >; Woodcock, Janet (FDA/CDER) (b) (6) >; Colvis, Christine (NIH/NCATS) [E] (b) (6) >; Desrosiers, Betsy (b) (6) >; Eric Hughes (b) (6) >; Jansen, Kathrin (b) (6) >; Kurilla, Michael (NIH/NCATS) [E] (b) (6) >; Lowy, Douglas (NCI) (b) (6) >; Read, Sarah (NIH/NIAID) [E] (b) (6) >; Young, John < (b) (6) >

Cc: Anderson, James (NIH/OD) [E] (b) (6) >; Austin, Christopher (NIH/NCATS) [E]

(b) (6) >; Burklow, John (NIH/OD) [E] < (b) (6) >; Castillejos, Carlos (b) (6) >; Culp, Michelle (NIH/OD) [E] (b) (6) >; FNIH Central Account (b) (6) >; Freire, Maria (FNIH) [T] < (b) (6) >; Gadbois, Ellen (NIH/OD) [E] < (b) (6) >; Hallett, Adrienne (NIH/OD) [E] (b) (6) >; Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Myles, Renate (NIH/OD) [E] (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) >; Tabak, Lawrence (NIH/OD) [E] < (b) (6) >; Wolinetz, Carrie (NIH/OD) [E] (b) (6) >; Gorman, Greta (FNIH) [T] (b) (6) >; Meltzer, Abbey (FNIH) [T] (b) (6) >; Myles, Renate (NIH/OD) [E] (b) (6) >; Wolinetz, Carrie (NIH/OD) [E] (b) (6) >; Adam, Stacey (FNIH) [T] (b) (6) >; Alvarez, Rosa Maria (b) (6) >; Margaret Anderson (b) (6) >; Appell, Evan < (b) (6) >; Chen, Helen Q. (b) (6) >; Elsaid, Olivia (b) (6) >; Gonzalez, Nina (b) (6) >; Hawk, Harrison (b) (6) >; Menetski, Joseph (FNIH) [T] (b) (6) >; Santos, Michael (FNIH) [T] < (b) (6) >; Stratton, Benjamin < (b) (6) >; btolman < (b) (6) >; Tountas, Karen (FNIH) [T] (b) (6) >; Wachtel, Jonathan (b) (6) >; Wholley, David (FNIH) [T] (b) (6) >

Subject: Materials for September 9 ACTIV Executive Committee Teleconference

Importance: High

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

(b) (6)

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United Kingdom

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Please let Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 1/12/2021 9:50:16 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6) ; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6) Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Erck, Stan [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John [(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aebc9a0d9b96c-NAR5]; Pandya, Hitesh [(b) (6) Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Reed, John [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [(b) (6) Tsai, John [(b) (6) Vessey, Rupert [(b) (6) Virgin, Skip [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Stratton, Benjamin [(b) (6) btolman [(b) (6) Wachtel, Jonathan [(b) (6) Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Bancel, Stephane [(b) (6) Meeker, David [(b) (6) Pangalos, Mene [(b) (6) Paul, Steve [(b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Togashi, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Underwood, Nancy [(b) (6) Zottoli, Jessica [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Magbie-Robinson, Kim (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Barasch, Kimberly (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Bell, Julie [(b) (6) Caulfield, Anita [(b) (6) Coan, Amanda [(b) (6) Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Edl, Susan (b) (6) Fuhrer, Nicole (b) (6) Giorgi, Sara (b) (6) Hoban, Michelle (b) (6) Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter]; Iberdemaj, Vaide (b) (6) Jenkins, Christine S. (b) (6) Lever, Susan (b) (6) Martin, Melisa (b) (6) McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Minnich, Beth (b) (6) Perala, Mie (b) (6) Protasiewicz, Ann (b) (6) Riccobene, Kim (b) (6) Riffin, Mary (b) (6) Ripley, Nadege (b) (6) Schuster, Donna (b) (6) Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Suhana, Tina (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fbb3e468057-esuhana]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Regan, Donna M (b) (6) Vessey, Rupert (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]

Subject: ACTIV Leadership Team Call #13
Attachments: ACTIV Joint Executive Committee & Leadership Team Meeting: tomorrow, February 17, 2021
Location: <https://fnih.zoom.us/> (b) (6)
Start: 2/17/2021 4:30:00 PM
End: 2/17/2021 6:00:00 PM
Show Time As: Busy

Required Attendees: Melencio, Cheryl (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Nasr, Hana; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan; Meltzer, Abbey (FNIH) [T]; Embry, Alan (NIH/NIAID) [E]

Optional Attendees: Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Magbie-Robinson, Kim; Simon, Dina (NIH/OD) [C]; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [E]; Bell, Julie; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lever, Susan; Martin, Melisa; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riffin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Suhana, Tina (NIH/VRC) [E];

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From: (b) (6) [(b) (6)]
Sent: 12/19/2020 12:30:30 AM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: Fwd: Notes from Wednesday's ACTIV Leadership Team Meeting
Attachments: 2020-12-16_ACTIV_Leadership_Team_and_Executive_Committee_Meeting_Summary_vF.docx; ATT00001.htm

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: (b) (6)

Begin forwarded message:

From: "Wholley, David (FNIH) [T]" (b) (6)
To: "Austin, Christopher (NIH/NCATS) [E]" < (b) (6) >, "Bancel, Stephane" (b) (6), "Carter, Kara" < (b) (6) >, "Cavalieri, Marco" (b) (6), "Cihlar, Tomas" < (b) (6) >, "Collins, Francis" (b) (6), "Corey, Larry" < (b) (6) >, "Culp, Michelle (NIH/OD) [E]" < (b) (6) >, "Victoria Davey" < (b) (6) >, "Disbrow, Gary" < (b) (6) >, "Dolsten, Mikael" < (b) (6) >, "Erbelding, Emily (NIH/NIAID) [E]" < (b) (6) >, "Erck, Stan" < (b) (6) >, "Fauci, Anthony (NIH/NIAID) [E]" < (b) (6) >, "Freire, Maria (FNIH) [T]" < (b) (6) >, "Gadbois, Ellen (NIH/OD) [E]" < (b) (6) >, "Gibbons, Gary (NIH/NHLBI) [E]" < (b) (6) >, "Hudson, Thomas" < (b) (6) >, "James, Stephanie (FNIH) [T]" < (b) (6) >, "Johnson, Robert (OS/ASPR/BARDA)" < (b) (6) >, "Kramer, Lynn" < (b) (6) >, "Lane, Cliff (NIH/NIAID) [E]" < (b) (6) >, "Lepore, John" < (b) (6) >, "Marks, Peter (FDA/CBER)" < (b) (6) >, "Marston, Hilary" < (b) (6) >, "Mascola, John (NIH/VRC) [E]" < (b) (6) >, "Meeker, David" < (b) (6) >, "Menetski, Joseph (FNIH) [T]" < (b) (6) >, "Messonnier, Nancy (CDC/DDID/NCIRD/OD)" < (b) (6) >, "Pandya, Hitesh" < (b) (6) >, "Pangalos, Mene" < (b) (6) >, "Pao, William" < (b) (6) >, "Parker, Ashley (NIH/OD) [E]" < (b) (6) >, "Paul, Steve" < (b) (6) >, "Perlmutter, Roger" < (b) (6) >, "Plenge, Robert" < (b) (6) >, "Plump, Andy" < (b) (6) >, "Rachel Ramoni" < (b) (6) >, "Reed, John" < (b) (6) >, "Reese, David" < (b) (6) >, "Rouse, Doris" < (b) (6) >, "Santos, Michael (FNIH) [T]" < (b) (6) >, "Skovronsky, Daniel" < (b) (6) >, "Stein, Peter (FDA/CDER)" < (b) (6) >, "Stoffels, Paul" < (b) (6) >, "Tabak, Lawrence (NIH/OD) [E]" < (b) (6) >, "Talley, Michael" < (b) (6) >, "Tsai, John" < (b) (6) >, "Vessey, Rupert" < (b) (6) >, "Virgin, Skip" < (b) (6) >, "Wholley, David (FNIH) [T]" < (b) (6) >, "Woodcock, Janet (FDA/CDER)" < (b) (6) >, "Young, John" < (b) (6) >, "Colvis, Christine" < (b) (6) >, "Desrosiers, Betsy" < (b) (6) >, "Eric Hughes" < (b) (6) >, "Jansen, Kathrin" < (b) (6) >, "Kurilla, Michael (NIH/NCATS) [E]" < (b) (6) >, "Lowy, Douglas (NCI)" < (b) (6) >, "Read, Sarah (NIH/NIAID) [E]" < (b) (6) >, "Young, John" < (b) (6) >, "Villafana, Tonya" < (b) (6) >
Cc: "Adam, Stacey (FNIH) [T]" < (b) (6) >, "Margaret Anderson" < (b) (6) >, "Appell, Evan" < (b) (6) >, "Chen, Helen" < (b) (6) >

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>, "Menetski, Joseph (FNIH) [T]" (b) (6) >, "Nasr, Hana"
(b) (6) "Santos, Michael (FNIH) [T]" (b) (6) "Sorosa, Alex David"
"Stratton, Benjamin" (b) (6) >, "btolman"
, "Tountas, Karen (FNIH) [T]" (b) (6) "Wachtel, Jonathan"
, "Wholley, David (FNIH) [T]" , "Anderson, James"
(NIH/OD) [E]" <(b) (6) "Austin, Christopher (NIH/NCATS) [E]"
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<(b) (6) "Castillejos, Carlos" (b) (6) >, "Culp, Michelle"
(NIH/OD) [E]" <(b) (6) "FNIH Central Account" (b) (6) >, "Gadbois,
Ellen (NIH/OD) [E]" (b) (6) >, "Hallett, Adrienne (NIH/OD) [E]"
(b) (6) , "Lane, Cliff (NIH/NIAID) [E]" (b) (6) >, "Myles, Renate"
(NIH/OD) [E]" (b) (6) "Parker, Ashley (NIH/OD) [E]" (b) (6) "Tabak,
Lawrence (NIH/OD) [E]" <(b) (6) "Wolinetz, Carrie (NIH/OD) [E]"
(b) (6) , "Burklow, John (NIH/OD) [E]" (b) (6) >, "Gorman, Greta"
(FNIH) [T]" (b) (6) >, "Hallett, Adrienne (NIH/OD) [E]" (b) (6)
"Meltzer, Abbey (FNIH) [T]" <(b) (6) "Myles, Renate (NIH/OD) [E]" (b) (6)
"Wolinetz, Carrie (NIH/OD) [E]" (b) (6)

Subject: Notes from Wednesday's ACTIV Leadership Team Meeting

Dear Leadership Team members and meeting attendees:

Please see the notes from our teleconference this past Wednesday, December 16. Please let me know of any additional comments, questions, or suggestions regarding these notes.

Thank you again for all your support of and contributions to ACTIV.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 4/22/2020 6:42:21 PM
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(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd];
(b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan];
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc];
(b) (6) (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56fdb4e598a57b423d484dcf9f-offit.email] (b) (6)
Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se];
(b) (6) Tal Zaks [(b) (6)
CC: Tolman, Brett [(b) (6) (b) (6) Hopps, Markay [(b) (6)
Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr];
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(b) (6) Isabel Ramsey [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; (b) (6)

(b) (6) Wachtel, Jonathan (b) (6) Arvin, Ann
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta]; Anderson, Margaret
 [(b) (6) Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Bethany Stokes
 (b) (6)]

Subject: ACTIV Vaccines Working Group meeting

Location: Webex: https://nih.webex. (b) (6)

Start: 5/5/2020 4:00:00 PM

End: 5/5/2020 5:00:00 PM

Show Time As: Tentative

Required Attendees: (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann;
 (b) (6) (b) (6) (b) (6) (b) (6)
 Emi (b) (6) (b) (6) Haynes, Barton; (b) (6)
 (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; Messonnier, Nancy
 (CDC/DDID/NCIRD/OD); Offit, Paul; (b) (6) Seals, Jonathan (OS/ASPR/BARDA);
 Jim. (b) (6) Tal Zaks
Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen
 (NIH/NCI) [E]; (b) (6) (b) (6) (b) (6)
 (b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker,
 Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Wholley, David (FNIH) [T];
 Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis,
 Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID)
 [E]; Young, John; Gonzalez, Nina; (b) (6) (b) (6) Wachtel,
 Jonathan; Arvin, Ann; Anderson, Margaret; Marston, Hilary (NIH/NIAID) [E]; Bethany Stokes

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
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Subject: Notes from the ACTIV Vaccines Working Group meeting
Attachments: 2020-11-11 Vaccines Working Group meeting Summary Notes.docx; 2020-11-11 Vaccines WG meeting.pptx

Dear Vaccines Working Group members,

With apologies for the delay, attached are notes and the single slide from last week's Vaccines Working Group meeting.

After the meeting, the Working Group and Sub-Group leadership aligned on the immediate priorities for discussion. Those begin today with the Vaccine Clinical Trial Sub-Group's meeting on evaluating the impact of vaccines on transmission. Topics prioritized for subsequent discussions include potential blinded cross-over for ongoing phase 3

trials, preparing for the possibility of vaccine efficacy varying by platform/product, and evaluating vaccines in immunocompromised populations. Invitations for meetings on those topics will be sent soon.

As always, we welcome addition comments and questions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, November 10, 2020 1:33 PM
Subject: Agenda for tomorrow's ACTIV Vaccines Working Group meeting

Dear Vaccines Working Group members,

We're looking forward to our next meeting, tomorrow (Wednesday) at 1pm ET / 10am PT / 7pm CET. We scheduled this meeting last week without knowledge of yesterday's exciting announcement, and are delighted to be re-convening this group at such an auspicious time.

As we described below, the agenda for tomorrow is an open discussion of the priorities for vaccines in addition to the licensure studies that the Vaccines Working Group or the Clinical Trials Sub-Group should consider. Some members of the group have already proposed a few ideas, and all members of the group are invited to make additional suggestions and weigh in on the potential opportunities. After the meeting we will prioritize next steps.

If you cannot attend tomorrow's meeting, as always please feel free to submit ideas in advance that we can share on your behalf or send feedback on the notes afterwards.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Friday, November 6, 2020 1:01 PM
Subject: Next ACTIV Vaccines Working Group meeting: Weds, 11 Nov

Dear Vaccines Working Group members,

As you may recall from the summer, we agreed to stop regular meetings of the Vaccines Working Group and reconvene as needed. Our next meeting will be Wednesday, 11 Nov, at 1pm ET (10am PT / 7pm CET).

We've been requested by ACTIV leadership to have a discussion about the priorities for vaccines in addition to the licensure studies. The Vaccines Clinical Trials Sub-Group has had previous meetings on the topics of evaluation in pregnant and pediatric populations, and is planning upcoming conversations about studying impact on transmission and evaluation in immunocompromised populations, as well as a discussion of the potential application of expanded access protocols.

At our next Working Group meeting, we would appreciate input on those and other potential priorities for discussion within the group. We are looking forward to your thoughts, and as always appreciate any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health

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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 6/8/2020 1:06:23 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Setup for Conference/Webex call re: monoclonal antibody combinatorial testing with Skip Virgin
Flag: Follow up

Dear Francis,

Do you want to have any of the working group experts on the call with Skip Virgin and Vir tomorrow? It seems like a lot of Vir folks, maybe they would be less forthcoming if we had others on the call.

I have not received any materials for this meeting.

Currently this is the invitee list.

Wholley, David (FNIH)
Collins, Francis (NIH/OD)
Woodcock, Janet (FDA/CDER)
Skip Virgin (Vir)
George Scangos (Vir)
Phil Pang (Vir)
Adam, Stacey (FNIH) [T]
Parker, Ashley (NIH/OD)
Graham, Barney (NIH/VRC)
Lane, Cliff (NIH/NIAID)
Menetski, Joseph (FNIH)

Joe

From: Menetski, Joseph (FNIH) [T] <(b) (6)>
Sent: Friday, June 5, 2020 6:44 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Wholley, David (FNIH) [T] <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)>
Subject: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

Dear Francis,

Stacey and I have polled our working groups, asking for suggestions and volunteers that could provide expert opinion on monoclonal antibody testing during conversations with Skip Virgin and Jacqueline Kirchner. The groups are very enthusiastic about this topic and we received almost 30 names of experts in the field. Given the time frame that we are asking for people to join these calls, I have picked 4 people that are already involved in ACTIV to invite to the Jacqueline Kirchner call tomorrow and 6 to invite to the call with Skip on Monday.

As I said, there were many more, but I think we would want to talk to them first, before bringing them into a discussion like this.

I am happy to invite these folks tonight, if it would be easier and agreeable to you (I would cc you). Or I have drafted a short email for you to send them below (as always, feel free to modify).

Best regards,
Joe

Memo: ACTIV discussion on choosing neutralizing antibodies and mixtures

Dear xx,

The NIH Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership is setting up protocols to assess monoclonal neutralizing antibodies as therapies against COVID-19. During discussions with the ACTIV Leadership Team and in collaboration with the upcoming Monoclonal Antibody Round Table, we have a meeting to gather additional expert opinion on the appropriate preclinical testing approaches, particularly for choosing mixtures or cocktails of neutralizing Abs. I would like to have your input in the important topic during a meeting [tomorrow at 1pm ET; or Monday at 2:45pm ET]. I realize this is short notice, but the ACTIV program is moving very fast and our rapid response is essential. I hope you can join me in this important discussion.

Sincerely,
Francis Collins

Names and emails below.

Saturday call with J Kirchner:

Peter Adams, (OS/ASPR/BARDA); (b) (6)
Michael Diamond at Washington University at St Louis; (b) (6)
Kara Carter at EvoTec; (b) (6)
John W Mellors at University of Pittsburgh; (b) (6)

Monday call with Skip Virgin:

Peter Adams, (OS/ASPR/BARDA); (b) (6)
Michael Diamond at Washington University at St Louis; (b) (6)
Kara Carter at EvoTec; (b) (6)
John W Mellors at University of Pittsburgh; (b) (6)
Randall Tressler, (NIH/NIAID); (b) (6)
Sebastian Breuer, Roche; (b) (6)

Joseph P. Menetski Ph.D.

Associate Vice President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6) | fnihi.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 1/16/2021 12:44:39 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [keith. (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [na (b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collis]; Amanda Peppercorn [(b) (6) Garner, Carl [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Lucas Smalldon [(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]

Subject: Summary of the ACTIV Therapeutics-Clinical Working Group

Attachments: 2021-01-14_TX-Clinical_WG_Meeting_Summary.pdf

Dear ACTIV TX-Clinical WG,

Thank you all for a very good discussion yesterday on the potential path forward for testing additional widely available agents. Please find attached the summary of the meeting if you have any additions or amendments, please let me know.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Foundation for the National Institutes of Health

Direct: (b) (6) | Mobile: (b) (6)

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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/9/2020 1:10:28 AM
To: Jim Neaton [(b) (6)]; Jens Lundgren [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Eric Hughes [(b) (6)]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Srinivasan, Badhri [(b) (6)]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Tierney, John (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61553b35beb7479789a06defda628627-jtierney]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [(b) (6)]; William Erhardt [(b) (6)]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; (b) (6) ; Gelijns, Annetine [(b) (6)]; Mark Polizzotto [(b) (6)]; Ginny Kan [(b) (6)]; Baker, Jason [(b) (6)]; Roger Paredes [(b) (6)]; Thompson, Taylor, M.D. [(b) (6)]; Babiker, Ab [(b) (6)]
CC: Chen, Helen Q. [(b) (6)]; Wachtel, Jonathan [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Desrosiers, Elizabeth A. [(b) (6)]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Kenny, Dermot [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Pett, Sarah [(b) (6)]; Grace, Beth (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75f1e9e678842258cf6472505f68cd8-bgrace]; Barrett, Kevin (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0490b8cf48984327b737d027f4fddd81-barrett2]; Denning, Eileen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc3c18df3b7945bda704a01abd12b3b4-eileen.ccb]r]
Subject: Materials for ACTIV-3 Operations Team Meeting
Attachments: ACTIV_TX-Clinical_ACTIV-3 Operations Team Meeting Agenda_20200609.pdf; INSIGHT014_ACTIV3_protocol_v0.4_8June2020.pdf

Dear ACTIV-3 Operations Team,

Please find attached the agenda for tomorrow's call and the current version of the ACTIV-3/TICO protocol. Please note that we are shortening the meeting by 15 minutes tomorrow to give those speaking and facilitating at the mAb Summit time to get organized and join that call a little early.

APAR0000005202-2517167

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

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Find your local number: <https://fnih.zoom.us/u> (b) (6)

From: Austin, Christopher (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=17597CABC42247548E596778304F781F-AUSTINC]
Sent: 10/16/2020 8:50:45 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: FW: 1st ACTIV-1 patient has been randomized
Flag: Follow up

Francis,
Thought you'd enjoy seeing this, came to me just as our Livestream ended.
And note it's WashU, where the trial PI (Bill Powderly) is, in case that's useful for Mr. Blunt.
Chris

From: Bozzette, Sam (NIH/NCATS) [E] <(b) (6)>
Sent: Friday, October 16, 2020 4:48 PM
To: Boucher, Cynthia (NIH/NCATS) [E] <(b) (6)> Atkinson, Jane (NIH/NCATS) [E] <(b) (6)> Chang, Soju (NIH/NCATS) [E] <(b) (6)> 'Sadeh, Jonathan' <(b) (6)> 'Gavin, Brian' <(b) (6)> 'Melsheimer, Rich [CNTNL]' <(b) (6)> 'Beumont-Mauviel, Maria [JRDUS]' <(b) (6)> 'Bharucha_David' <(b) (6)> 'Ferguson_William' <(b) (6)> Eric Hughes <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> 'LaVange, Lisa M' <lisa.(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Gardner, Bobbi (NIH/NCATS) [E] <(b) (6)> 'Sandeep Menon' <(b) (6)> 'Yong, Florence H' <(b) (6)> 'Trank, Christina' <(b) (6)> 'Moyo, Vusi' <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> 'Kimmel, Bridget [JRDUS]' <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Marti, Emily (NIH/NCATS) [E] <(b) (6)> Eisnor, Derek (OS/ASPR/BARDA) <(b) (6)> ' (b) (6)' <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> Woodcock, Janet (FDA/CDER) <(b) (6)> Mason, Robin (OS/ASPR/BARDA) <(b) (6)>
Cc: 'Montgomery, Stephanie' <(b) (6)> O'Sullivan_Alexandra <(b) (6)> Stock, Thomas (HHS/IOS) <(b) (6)> Neta Nelson <(b) (6)> Butler, Sandy <(b) (6)> Daniel Benjamin Jr, M.D., Ph.D. <(b) (6)> Theresa Jasion <(b) (6)> Molina, Daniel <(b) (6)> Rose Beci <(b) (6)> Lind, Brian (NIH/NCATS) [E] <(b) (6)> Mason, Robin (OS/ASPR/BARDA) <(b) (6)> O'rourke, Anna (OS/ASPR/BARDA) (CTR) <Anna.(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Lori Hudson, Ph.D. <(b) (6)> "Huyen Cao" <(b) (6)> "Huyen Cao" <(b) (6)> Huyen Cao <(b) (6)> Brody, Betty (OS/ASPR/BARDA) <(b) (6)> Chiang, Anna (OS/ASPR/BARDA) <(b) (6)> Schmidt, Jeffrey (OS/ASPR/BARDA) <(b) (6)>
Subject: 1st ACTIV-1 patient has been randomized

Hello:

The first patient has been randomized into ACTIV-1. Congratulations to all, especially Bill Powderly, Jane O'Halloran, and the rest of the Wash U team.

Happy weekend to all!
Sam B

Sam Bozzette, MD, PhD
Chief Medical Officer

COLL0000013979-2517168

*Immediate Office of the Director
National Center for Advancing Translational Sciences
National Institutes of Health*

*6701 Democracy Blvd., Room 926
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(Use ZIP code 20817 for overnight mail or courier)

Phone: () (b) (6)

E-mail: (b) (6)

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

From: Kara Carter [(b) (6)]
Sent: 8/4/2020 6:21:53 PM
To: Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m; (b) (6); (b) (6); (b) (6); (b) (6); Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6); (b) (6); (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

Subject: RE: ACTIV Preclinical full working group

Clint,

Thanks for sending this paper around. I was just reading it myself. Do you know what dose levels of REGN10987+REGN10933 are included in the high and low doses of the cocktail (REGN-COV2) that are currently in clinical trials? I think it is interesting that the doses are not defined on clinicaltrials.gov.

Kara



Kara Carter, PhD

Executive Vice President Infectious Disease

(b) (6) (Mobile)

(b) (6)

www.evotec.com

From: Florence, Clint (NIH/NIAID) [E] < (b) (6) >

Sent: Tuesday, August 4, 2020 1:28 PM

To: Menetski, Joseph (FNIH) [T] < (b) (6) > Hild, Sheri (NIH/OD) [E] < (b) (6) >

< (b) (6) > (b) (6) < (b) (6) > (b) (6) Kara Carter

< (b) (6) > (b) (6) < (b) (6) > (b) (6) Baric, Ralph

< (b) (6) > (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E]

< (b) (6) > Colvis, Christine (NIH/NCATS) [E] < (b) (6) > Hewitt, Judith (NIH/NIAID)

[E] < (b) (6) > Deming, Damon (FDA/CDER) < (b) (6) > (b) (6)

(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) > Collins, Francis

(NIH/OD) [E] < (b) (6) > (b) (6) Adams, Peter (OS/ASPR/BARDA)

< (b) (6) > Rao, Srinivas < (b) (6) > Qashu, Felicia (NIH/OD) [E]

< (b) (6) Tomas Cihlar < (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) < (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] < (b) (6) Charette, Marc (NIH/NHLBI) [E] < (b) (6) Fessel, Josh (NIH/NHLBI) [E] < (b) (6) (b) (6) Wholley, David (FNIH) [T] < (b) (6) Austin, Christopher (NIH/NCATS) [E] < (b) (6) Melencio, Cheryl (FNIH) [T] < (b) (6) Colvis, Christine (NIH/NCATS) [E] < (b) (6) Desrosiers, Betsy < (b) (6) Eric Hughes < (b) (6) Jansen, Kathrin < (b) (6) Kurilla, Michael (NIH/NCATS) [E] < (b) (6) Lowy, Douglas (NCI) < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) James, Stephanie (FNIH) [T] < (b) (6) Alvarez, Rosa Maria < (b) (6) Kim, Elizabeth < (b) (6) Tolman, Brett < (b) (6) Wachtel, Jonathan < (b) (6) Prabhavathi Fernandes < (b) (6) Diamond, Michael < (b) (6) Rose Li < (b) (6) Dana Carluccio < (b) (6) Lagos, Enrique (NIH/NCATS) [E] < (b) (6) Jonson, Samantha (NIH/NCATS) [E] < (b) (6) Gonzalez, Nina < (b) (6) Simon, Dina (NIH/OD) [C] < (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] < (b) (6) Rodriguez, Robin D < (b) (6) Dave Frankowski < (b) (6) Baric, Toni C < (b) (6) Lowy, Douglas (NIH/NCI) [E] < (b) (6) Florence, Clint (NIH/NIAID) [E] < (b) (6) Nancy Haigwood < (b) (6) Stratton, Benjamin < (b) (6) Gadbois, Ellen (NIH/OD) [E] < (b) (6) Anderson, James (NIH/OD) [E] < (b) (6)

Subject: Re: ACTIV Preclinical full working group

[EXTERNAL]

FYI

From: (b) (6)

When: 10:00 AM - 11:00 AM July 29, 2020

Subject: ACTIV Preclinical full working group

Location: <https://ddec1-0-en->

[ctp.trendmicro.com:4](https://ddec1-0-en-)

(b) (6)

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Changing time for preclinical WG

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg];

Gonzalez, Nina [(b) (6) Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) ; Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [(b) (6) Mason, Stephen (b) (6) (b) (6)

Start: 9/23/2020 2:30:00 PM
End: 9/23/2020 3:30:00 PM
Show Time As: Tentative

Recurrence: (none)

Required Attendees: Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6) (b) (6)
(b) (6) kara. (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
(b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E];
Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E];
Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)

Changing time for this meeting at the request of the cochair.

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

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US (Chicago)
US (New York)
JS (San Jose)
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US (Tacoma)
US (Houston)

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Passcode: (b) (6)

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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 8/3/2020 9:40:41 PM
To: Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m; (b) (6); (b) (6); (b) (6); (b) (6); (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6); (b) (6); (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio

[(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Caroline Sferrazza [(b) (6)

Subject: RE: ACTIV Preclinical full working group
Attachments: 2020-07-29_Preclinical_WG_Summary_f1.docx

Dear Working group and Attendees,

Please find the minutes from last weeks meeting for your review.

Let me know if you have any questions.

Best regards,
joe

Joseph P. Menetski Ph.D.
Associate Vice President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6) | fnihi.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnihi.org/pandemic



From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 9/25/2020 4:57:20 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [(b) (6) Dolsten, Mikael [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [(b) (6)]; Gibbons, Gary (NIH/NHLBI) [E] [(b) (6) Marks, Peter (FDA/CBER) [(b) (6)]; Pao, William [(b) (6) Plump, Andrew [(b) (6) Stoffels, Paul (b) (6) ; Woodcock, Janet (FDA/CDER) [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Eric Hughes [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Desrosiers, Betsy [(b) (6) Young, John (b) (6)

CC: Adam, Stacey (FNIH) [T] [(b) (6) Alvarez, Rosa Maria [(b) (6) Margaret Anderson [(b) (6) Appell, Evan [(b) (6) Chen, Helen Q. [(b) (6) Gonzalez, Nina [(b) (6) Hawk, Harrison [(b) (6)]; Mendelson, Jesse (b) (6) Menetski, Joseph (FNIH) [T] [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Stratton, Benjamin [(b) (6)]; btolman [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Wachtel, Jonathan [(b) (6) Wholley, David (FNIH) [T] [(b) (6)]; Barasch, Kimberly (NIH/NIAID) [C] [(b) (6)]; Conrad, Patricia (NIH/NIAID) [E] [(b) (6) .gov]; Dimishkov, Roxanne (NIH/NHLBI) [C] [(b) (6)]; McManus, Ayanna (NIH/OD) [E] [(b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann [(b) (6) Thomas, Ashley (FDA/CDER) [(b) (6) Wood, Gretchen (NIH/OD) [E] [(b) (6) Anderson, James (NIH/OD) [E] [(b) (6) Austin, Christopher (NIH/NCATS) [E] [(b) (6) Burklow, John (NIH/OD) [E] [(b) (6) Carluccio, Dana [(b) (6) Castillejos, Carlos [(b) (6) Culp, Michelle (NIH/OD) [E] [(b) (6) FNIH Central Account [(b) (6) Freire, Maria (FNIH) [T] [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6) Hallett, Adrienne (NIH/OD) [E] [(b) (6) Lane, Cliff (NIH/NIAID) [E] [(b) (6) Myles, Renate (NIH/OD) [E] [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Tabak, Lawrence (NIH/OD) [E] [(b) (6)]; Wolinetz, Carrie (NIH/OD) [E] [(b) (6)]; Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6) Carver, Trea (NIH) [C] [(b) (6) Hughes, Karen (NIH/OD) [E] [(b) (6)]; Lagos, Enrique (NIH/NCATS) [E] [(b) (6)]; Sepulveda, Dorina (FNIH) [T] [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6) Tajalli, Ada (NIH/OD) [E] [(b) (6)]; Gorman, Greta (FNIH) [T] [(b) (6) Meltzer, Abbey (FNIH) [T] [(b) (6) Togashi, Mieko (NIH/NCI) [E] [(b) (6) Underwood, Nancy [(b) (6) Zottoli, Jessica [(b) (6) Sorosa, Alex [(b) (6) Connelly, Sarah [(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6) Riccobene, Kim [(b) (6) Hamilton, Nancy [(b) (6)

Subject: ACTIV EC & Working Group Co-Chair Meeting

Location: <https://fnih.zoom.us/> (b) (6)

Start: 11/4/2020 3:00:00 PM

End: 11/4/2020 4:00:00 PM

Show Time As: Busy

Required Attendees: Melencio, Cheryl (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John

Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Appell, Evan; Chen, Helen; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett;

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/22/2020 2:51:23 PM
To: Jim Neaton [(b) (6)]; Jens Lundgren [(b) (6)]; Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Karen Lynn Price [(b) (6)]; LaVange, Lisa M [(b) (6)]; Sandeep Menon [(b) (6)]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80023e7be2dd4554b54d1604fa60df18-rachel.h.ha]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; [(b) (6)]; Gelijns, Annetine [(b) (6)]; Moskowitz, Alan [(b) (6)]; Ab Babiker [(b) (6)]; Cavan, Reilly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=995fe0f1a53c443a832f96f003f0f2c5-cavanr.bios]; Phillips, Andrew [(b) (6)]; [(b) (6)]; Birgit Grund [(b) (6)]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f2b26b051964d9da6868e53c9cc6c49-jim.ccbr.um]; Joe Koopmeiners [(b) (6)]; David Vock [(b) (6)]; Thomas Murray [(b) (6)]; Max Parmar [(b) (6)]; Mark Polizzotto [(b) (6)]; Ginny Kan [(b) (6)]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Baker, Jason [(b) (6)]; Roger Paredes [(b) (6)]; [(b) (6)]; [(b) (6)]; M [(b) (6)]; [(b) (6)]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; [(b) (6)]; [(b) (6)]; Ajay Nirula [(b) (6)]; Paul Klekotka [(b) (6)]; Ginde, Adit [(b) (6)];
CC: Demarcus [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Chen, Helen Q. [(b) (6)]; Eron, Joseph J Jr [(b) (6)]; Chew, Kara M.D. [(b) (6)]; Daar, Eric [(b) (6)]; Bagiella, Emilia [(b) (6)]; [(b) (6)]; Lisbeth Jørgensen [(b) (6)]; Erhardt, William (HHS/IOS) [(b) (6)];
Subject: ACTIV-3 Writing Team Meeting
Attachments: ACTIV_TX-Clinical_ACTIV-3 Writing Team Meeting Agenda_20200622.pdf
Location: <https://fnih.zoom.us/> [(b) (6)]
Start: 6/22/2020 3:00:00 PM

End: 6/22/2020 4:00:00 PM

Show Time As: Tentative

Required Attendees: Jim Neaton; Jens Lundgren; Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA); Patterson, Amy (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Reineck, Lora (NIH/NHLBI) [E]; Judy Currier; Karen Lynn Price; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; Erhardt, William (OS/ASA/OCIO/DCIO-Ops) (CTR);
(b) (6) Gelijns, Annetine; Moskowitz, Alan; Ab Babiker; Cavan, Reilly; Phillips, Andrew
(b) (6) Birgit Grund; Neaton, Jim; Joe Koopmeiners; David Vock; Thomas Murray; Max Parmar; Mark Polizzotto; Ginny Kan; Lane, Cliff (NIH/NIAID) [E]; Baker, Jason; Roger Paredes; (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6) Rosenberg, Yves (NIH/NHLBI) [E]; (b) (6) (b) (6) Ajay Nirula; Paul Klekotka; Ginde, Adit
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Parker, Ashley (NIH/OD) [E]; Chen, Helen Q.; Eron, Joseph J Jr; Chew, Kara M.D.; Daar, Eric; Bagiella, Emilia; (b) (6) Lisbeth Jørgensen; Erhardt, William (HHS/IOS)

Dear ACTIV-3 Writing Team,

Please see a high level agenda for today's call.

Thanks,
Stacey

Join Zoom Meeting

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Find your local number: <https://fnih.zoom.us/> (b) (6)

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]
Sent: 3/4/2021 8:23:08 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Thompson, Katherine (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f2c78f864ae43558adb82dc6b9a4d71-thompsonkap]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]
Subject: RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Hi David:

We list the Executive Committee on the ACTIV page and can replace Andy with Rajev on the [organization chart](#) and this [Executive Committee governance](#) page. We don't actually list the leadership on the ACTIV page.

Cheryl: will you be coordinating as per usual to see if these folks agree to be listed on the page and how they want to be listed?

Thanks,
Renate

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Thursday, March 4, 2021 2:54 PM
To: Wholley, David (FNIH) [T] <(b) (6)>; Myles, Renate (NIH/OD) [E] <(b) (6)>; Meltzer, Abbey (FNIH) [T] <(b) (6)>; Thompson, Katherine (FNIH) [T] <(b) (6)>
Cc: Freire, Maria (FNIH) [T] <(b) (6)>; Santos, Michael (FNIH) [T] <(b) (6)>; Melencio, Cheryl (FNIH) [T] <(b) (6)>; Meltzer, Abbey (FNIH) [T] <(b) (6)>; Parker, Ashley (NIH/OD) [E] <(b) (6)>; Gonzalez, Nina <(b) (6)>; Appell, Evan <(b) (6)>
Subject: RE: Notes from Wednesday's ACTIV Leadership Team Meeting

I'm fine with that plan.

FC

From: Wholley, David (FNIH) [T] (b) (6) >
Sent: Thursday, March 4, 2021 1:08 PM
To: Myles, Renate (NIH/OD) [E] (b) (6) >; Meltzer, Abbey (FNIH) [T] < (b) (6) >; Thompson, Katherine (FNIH) [T] (b) (6)
Cc: Freire, Maria (FNIH) [T] (b) (6); Santos, Michael (FNIH) [T] (b) (6) >; Melencio, Cheryl (FNIH) [T] (b) (6); Meltzer, Abbey (FNIH) [T] (b) (6) >; Collins, Francis (NIH/OD) [E] (b) (6); Parker, Ashley (NIH/OD) [E] (b) (6); Gonzalez, Nina (b) (6); Appell, Evan (b) (6)
Subject: FW: Notes from Wednesday's ACTIV Leadership Team Meeting

Can we please add Gary Dubin to the Vaccine WG rosters on the NIH and FNIH websites, and substitute Rajeev Venkayya for Andy Plump as the rep for Takeda to the ACTIV Leadership Team?

Francis, I am assuming this means Andy is also asking that Rajeev replace him on the Executive Committee. He's got a good background for PPPs—worked for four years on the WH biodefense team (wherefrom he knows Tony Fauci), is Andy's counterpart at Takeda as global head of their vaccines business, directed vaccines delivery at BMGF, and serves on the boards of SEPI and IAVI. I found him engaging and impressive, and am guessing Mike did too.

Thanks, David

From: Burke, Leslie < (b) (6) > **On Behalf Of** Venkayya, Rajeev
Sent: Thursday, March 4, 2021 12:03 PM
To: Santos, Michael (FNIH) [T] (b) (6)
Cc: Wholley, David (FNIH) [T] < (b) (6) >; Melencio, Cheryl (FNIH) [T] < (b) (6) >; Venkayya, Rajeev (b) (6)
Subject: RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Dear Mike,

I'm following up on Rajeev's behalf to let you know he would like to recommend his colleague **Gary Dubin, MD** (b) (6) for the Vaccines WG. Gary is the Head of our Global Medical Office, and leads the Takeda Vaccine Business Medical Affairs and Policy team. (b) (6) is his Executive Assistant.

Gary will look forward to connecting!

Please don't hesitate to reach out with any questions.

Many thanks,

Leslie Burke

EA to Rajeev Venkayya, MD, President, Global Vaccine Business Unit
Vaccine Business Unit

Takeda Pharmaceutical Company Limited

Mail to: 40 Landsdowne Street, Cambridge, MA 02139, USA

Office location: 75 Sidney Street, Cambridge, MA 02139, USA

mobile: (b) (6)

email: (b) (6) | www.takedavaccines.com

From: Santos, Michael (FNIH) [T] (b) (6)
Sent: Monday, March 1, 2021 12:04 PM
To: Venkayya, Rajeev (b) (6)
Cc: Wholley, David (FNIH) [T] (b) (6); Melencio, Cheryl (FNIH) [T] (b) (6) >; Burke, Leslie (b) (6)
Subject: RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Be advised that this email came from outside Takeda / お知らせ:社外から送信されたメールです

Hi Rajeev,

It was great meeting and chatting. Your experience and perspectives are a great addition to the group.

As we discussed, attached are notes from the last few Vaccines WG meetings. The meetings are not under NDA, but our principle is that information shared during the meetings should only be used to advanced the shared objective of supporting COVID-19 vaccine development. So please feel free to share with the relevant people in your team, but not publicly.

If anyone is interested in joining the Vaccines Working Group, please let us know and we'll be happy to add them.

Best regards,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Venkayya, Rajeev (b) (6)
Sent: Friday, February 19, 2021 11:21 PM
To: Santos, Michael (FNIH) [T] (b) (6)
Cc: Wholley, David (FNIH) [T] <(b) (6)>; Melencio, Cheryl (FNIH) [T] (b) (6) >; Burke, Leslie (b) (6)
Subject: Re: Notes from Wednesday's ACTIV Leadership Team Meeting

Dear Michael,

Thanks for the kind introduction and background. I know FNIH well and am looking forward to working with you. And yes, I'm sure we have many colleagues in common from BMGF!

An onboarding call would be helpful if it's not too much trouble. I'll ask Leslie to work with you to set that up. I look forward to that, and to meeting the ACTIV group!

Regards,

Rajeev

From: Santos, Michael (FNIH) [T] (b) (6)
Sent: Friday, February 19, 2021 4:59:22 PM
To: Venkayya, Rajeev <(b) (6)>

Cc: Wholley, David (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)>
Subject: RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Be advised that this email came from outside Takeda / お知らせ:社外から送信されたメールです

Dear Rajeev,

We heard from Andy Plump and Francis Collins that you are joining ACTIV. We're delighted to have you on the team.

The Foundation for the NIH manages ACTIV; David Wholley leads our work overall, I manage the Vaccines Working Group, and my counterparts manage the other Working Groups. If you are interested, we would be happy to have a call to provide context on ACTIV and the Vaccines Working Group and answer any questions that you have.

On a personal note, I was at BMGF for almost 6 years on the Discovery and HIV teams before I joined FNIH in late 2019. Although we missed overlapping there, I'm sure we know many people in common and I hope that we'll have the opportunity to connect sometime.

Best regards,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Friday, February 19, 2021 4:07 PM
To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Bancel, Stephane
<(b) (6)> Carter, Kara <(b) (6)> >; Cavaleri, Marco
<(b) (6)> Cihlar, Tomas <(b) (6)> >; Collins, Francis (NIH/OD) [E]
<(b) (6)> Corey, Larry <(b) (6)> >; Culp, Michelle (NIH/OD) [E] <(b) (6)>
Victoria Davey <(b) (6)> >; Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> >; Dolsten, Mikael
<(b) (6)> >; Embry, Alan (NIH/NIAID) [E] <(b) (6)> >; Erbeling, Emily (NIH/NIAID) [E]
Erck, Stan <(b) (6)> >; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>
Freire, Maria (FNIH) [T] <(b) (6)> >; Gadbois, Ellen (NIH/OD) [E] <(b) (6)> >; Gibbons, Gary
(NIH/NHLBI) [E] <(b) (6)> >; Hudson, Thomas <(b) (6)> >; James, Stephanie (FNIH) [T]
<(b) (6)> >; Johnson, Robert (OS/ASPR/BARDA) <(b) (6)> >; Kramer, Lynn
<(b) (6)> >; Lane, Cliff (NIH/NIAID) [E] <(b) (6)> >; Lepore, John <(b) (6)>
Marks, Peter (FDA/CBER) <(b) (6)> >; Mascola, John (NIH/VRC) [E] <(b) (6)> >; Meeker,
David <(b) (6)> >; Menetski, Joseph (FNIH) [T] <(b) (6)> >; Messonnier, Nancy
(CDC/DDID/NCIRD/OD) <(b) (6)> >; Pandya, Hitesh <(b) (6)> >; Pangalos, Mene
<(b) (6)> >; Pao, William <(b) (6)> >; Parker, Ashley (NIH/OD) [E]
<(b) (6)> >; Paul, Steve <(b) (6)> >; Perlmutter, Roger <(b) (6)> >;
Plenge, Robert <(b) (6)> >; Reed, John <(b) (6)> >; Reese, David <(b) (6)>
Rouse, Doris <(b) (6)> >; Santos, Michael (FNIH) [T] <(b) (6)> >; Skovronsky, Daniel
<(b) (6)> >; Stein, Peter (FDA/CDER) <(b) (6)> >; Stoffels, Paul
<(b) (6)> >; Tabak, Lawrence (NIH/OD) [E] <(b) (6)> >; Talley, Michael
<(b) (6)> >; Tsai, John <(b) (6)> >; Venkayya, Rajeev <(b) (6)>
Vessey, Rupert <(b) (6)> >; Virgin, Skip <(b) (6)> >; Wholley, David (FNIH) [T] <(b) (6)> >;
Woodcock, Janet (FDA/OC) <(b) (6)> >; Young, John <(b) (6)> >; Colvis,
Christine (NIH/NCATS) [E] <(b) (6)> >; Desrosiers, Betsy <(b) (6)> >; Eric
Hughes <(b) (6)> >; Jansen, Kathrin <(b) (6)> >; Kurilla, Michael (NIH/NCATS) [E]
<(b) (6)> >; Lowy, Douglas (NCI) <(b) (6)> >; Read, Sarah (NIH/NIAID) [E] <(b) (6)> >;
Young, John <(b) (6)> >; Adam, Stacey (FNIH) [T] <(b) (6)> >; Margaret Anderson

< (b) (6) Appell, Evan (b) (6) >; Chen, Helen <qi (b) (6)
Connelly, Sarah < (b) (6) >; Dally, Nicolle (b) (6) >; Gonzalez, Nina
(b) (6) >; Hawk, Harrison (b) (6) >; Mendelson, Jesse (b) (6)
Menetski, Joseph (FNIH) [T] (b) (6) >; Nasr, Hana < (b) (6) >; Santos, Michael (FNIH) [T]
(b) (6) >; Sorosa, Alex (b) (6) >; Stratton, Benjamin (b) (6) m>; Tolman,
Brett (b) (6) >; Wachtel, Jonathan (b) (6) >; Wholley, David (FNIH) [T]
< (b) (6) >; Plump, Andrew (b) (6)
Cc: Anderson, James (NIH/OD) [E] (b) (6) >; Burklow, John (NIH/OD) [E] (b) (6) >;
Carluccio, Dana (b) (6) >; Castillejos, Carlos (b) (6) >; FNIH Central Account
< (b) (6) >; Lumsden, Joanne (NIH/NCATS) [C] (b) (6) >; Hallett, Adrienne
(NIH/OD) [E] (b) (6) >; Meltzer, Abbey (FNIH) [T] (b) (6) >; Myles, Renate (NIH/OD) [E]
(b) (6) >; Wolinetz, Carrie (NIH/OD) [E] (b) (6) >
Subject: Notes from Wednesday's ACTIV Leadership Team Meeting

Dear Leadership Team members and meeting attendees:

Please see the notes from our teleconference this past Wednesday, February 17. Please let me know of any additional comments, questions, or suggestions regarding these notes.

Thank you again for all your support of and contributions to ACTIV.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Churity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/16/2020 9:58:35 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6) Wung, Peter /US [(b) (6) Karen Lynn Price [(b) (6) Pamela Tenaerts, M.D. [(b) (6) Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy [(b) (6) Beumont-Mauviel, Maria [JRDU] [(b) (6) Peeters, Monika [JRDBE] [(b) (6) Woodfall, Brian [JRDU] [(b) (6) Van Heeswijk, Rolf [JRDBE] [(b) (6)
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Follow-up to ACTIV TX-Clinical Master Protocol Subgroup Meeting #17
Attachments: ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 15May2020_Key Takeaways.pdf

Dear ACTIV TX-Clinical Master Protocol Subgroup,

Please find attached the action items and summary notes for yesterday's meeting. Please let us know if you have any additions or amendments.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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From: Charette, Marc (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A7FA2BAF951848B5BF1F76A049A0ECA6-CHARETTEMF]
Sent: 6/23/2020 1:24:30 PM
To: Alvarez, Rosa Maria [(b) (6)] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp];
 (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) [(b) (6)] (b) (6) [(b) (6)]
 (b) (6) [(b) (6)] Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
 (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Diamond, Michael [(b) (6)] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6)] Hughes, Eric [(b) (6)] Jansen, Kathrin [(b) (6)] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [(b) (6)] Tolman, Brett [(b) (6)] Wachtel, Jonathan [(b) (6)] Prabhavathi Fernandes [(b) (6)] Rose Li [(b) (6)] Dana Carluccio [(b) (6)] Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6)] Dave Frankowski [(b) (6)] Baric, Toni C [(b) (6)] Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood

[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
[(b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas
[(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar
[(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6)
Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Fessel, Josh (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]

Subject: RE: ACTIV Preclinical full working group

Attachments: ACTIV Pandemic Response Development Manuscript_20200622_Abtract with MC suggestions 062320.docx

Hello everyone,

Perhaps it is too early, but I have made some suggested changes to the abstract.

Most are stylist but some are for readability.

Best,

Marc Charette, Ph.D.

Program Director

Vascular Biology and Hypertension Branch

Division of Cardiovascular Sciences

Director

Vascular Interventions/Innovations and Therapeutic Advances (VITA) Program



National Heart, Lung,
and Blood Institute

6705 Rockledge Drive
Rockledge Center One, workspace 313M
Bethesda, MD 20892
301-435-0527

(b) (6)

From: Alvarez, Rosa Maria < (b) (6) >

Sent: Monday, June 22, 2020 6:55 PM

To: Menetski, Joseph (FNIH) [T] < (b) (6) > (b) (6) Hild, Sheri (NIH/OD) [E]

< (b) (6) > (b) (6) (b) (6) (b) (6)

(b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph

< (b) (6) > (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E]

< (b) (6) > Colvis, Christine (NIH/NCATS) [E] < (b) (6) > Hewitt, Judith (NIH/NIAID)

GADB0000003152-2517176

[E] < (b) (6) Culp, Michelle (NIH/OD) [E] < (b) (6) Gadbois, Ellen (NIH/OD) [E]
 < (b) (6) Diamond, Michael < (b) (6) Wholley, David (FNIH) [T] < (b) (6)
 Austin, Christopher (NIH/NCATS) [E] < (b) (6) Melencio, Cheryl (FNIH) [T] < (b) (6)
 Desrosiers, Betsy < (b) (6) Hughes, Eric < (b) (6) Jansen, Kathrin
 < (b) (6) Kurilla, Michael (NIH/NCATS) [E] < (b) (6) Lowy, Douglas (NCI)
 < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6)
 Santos, Michael (FNIH) [T] < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) James, Stephanie (FNIH)
 [T] < (b) (6) Kim, Elizabeth < (b) (6) Tolman, Brett < (b) (6) Wachtel,
 Jonathan < (b) (6) Prabhavathi Fernandes < (b) (6) Rose Li
 < (b) (6) Dana Carluccio < (b) (6) Lagos, Enrique (NIH/NCATS) [E]
 < (b) (6) Jonson, Samantha (NIH/NCATS) [E] < (b) (6) Gonzalez, Nina
 < (b) (6) Simon, Dina (NIH/OD) [C] < (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E]
 < (b) (6) Rodriguez, Robin D < (b) (6) Dave Frankowski
 < (b) (6) Baric, Toni C < (b) (6) Lowy, Douglas (NIH/NCI) [E]
 < (b) (6) Florence, Clint (NIH/NIAID) [E] < (b) (6) Nancy Haigwood
 < (b) (6) Stratton, Benjamin < (b) (6) Deming, Damon (FDA/CDER)
 < (b) (6) (b) (6) (b) (6) (b) (6) Parker,
 Ashley (NIH/OD) [E] < (b) (6) Collins, Francis (NIH/OD) [E] < (b) (6)
 (b) (6) Adams, Peter (OS/ASPR/BARDA) < (b) (6) Rao, Srinivas
 < (b) (6) Qashu, Felicia (NIH/OD) [E] < (b) (6) Tomas Cihlar
 < (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) < (b) (6)
 Punturieri, Antonello (NIH/NHLBI) [E] < (b) (6) Charette, Marc (NIH/NHLBI) [E]
 < (b) (6) Fessel, Josh (NIH/NHLBI) [E] < (b) (6)

Subject: RE: ACTIV Preclinical full working group

Hi all,

Apologies – We sent an earlier version of the abstract. Attached for the **latest abstract** of the Pandemic Response Drug Development Manuscript.

Please let us know if you have any feedback.

Best regards,
 Rosa

Rosa M. Álvarez
 Deloitte Consulting LLP
 Mobile: (b) (6)
www.deloitte.com

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] <(b) (6)>

Sent: Tuesday, April 14, 2020 6:44 PM

To: Menetski, Joseph (FNIH) [T], (b) (6); Hild, Sheri (NIH/OD) [E]; (b) (6)

(b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6); Baric, Ralph; (b) (6) Ottinger, Elizabeth (NIH/NCATS
 [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER);
 (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis
 (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD)
 [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E];
 Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]

Cc: Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Diamond, Michael; Wholley, David (FNIH) [T]; Austin,
 Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla,
 Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael

(FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin

Subject: ACTIV Preclinical full working group

When: Wednesday, June 17, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us/j> (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/14/2020 1:24:32 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [(b) (6) Butterson, Joan [(b) (6) Collins, Sylva (FDA/CDER) [Sylva. (b) (6)]; Judy Currier [(b) (6) .edu]; De Claro, R. Angelo (FDA/CDER) [(b) (6) Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [(b) (6) Rubin, Daniel B. (FDA/CDER) [(b) (6) Shen, Yuan Li (FDA/CDER) [(b) (6)]
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] (b) (6)]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b224466140faa95aaaaf06ebd70-parkeras]; Rose Li Central Account [(b) (6) Lucas Smalldon [(b) (6) Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] (b) (6) ; Melencio, Cheryl (FNIH) [T] (b) (6)
Subject: ACTIV TX-Clinical WG Master Protocol Subgroup -1st Meeting
Attachments: ACTIV TX-Clinical WG Master Protocol Subgroup -1st Meeting; NIH workstream Consortium leadrnings (002).pptx
Location: [https://zoom.us/j/\(b\) \(6\) 9](https://zoom.us/j/(b) (6) 9)
Start: 4/15/2020 5:30:00 PM
End: 4/15/2020 6:30:00 PM
Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER)
Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Rose Li Central Account; Lucas Smalldon; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

Dear ACTIV Therapeutics-Clinical WG Master Protocol Subgroup Members,

Thank you for your interest and participation in the Master Protocol sub-group. We are appreciative of your time and look forward to a focused discussion on the development of COVID-19 Master Protocols.

Our first meeting will take place today, Wednesday April 15th from 1:30pm-2:30pm ET. Dial-in instructions are below, similar to the zoom call on Monday. We wanted to notify you promptly of the meeting time and will follow up with an agenda and any necessary materials prior to the call.

Please note that this is not a fixed timeslot for upcoming sub-group meetings. After this first sub-group meeting, we will send out a scheduling link to coordinate the best time for sub group meetings moving forward.

Kind regards,
Stacey, on behalf of the ACTIV TX-Clinical WG

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From: Stan Erck [(b) (6)]
Sent: 7/10/2020 10:35:05 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Mary Riggini [(b) (6)]
Subject: Re: Invitation to Join ACTIV Leadership Team

Francis, thanks for the invitation. I would be happy to join. I'm cc'ing Mary Riggini who is the master of my schedule. Look forward to it. And, I'd prefer "Stan" to Mr. Erck. Look forward to seeing you.

Best, Stan

From: "Collins, Francis (NIH/OD) [E]" < (b) (6) >
Date: Thursday, July 9, 2020 at 10:23 PM
To: Stan Erck < (b) (6) >
Cc: "Wholley, David (FNIH) [T]" < (b) (6) >
Subject: Invitation to Join ACTIV Leadership Team

[SENDER IS EXTERNAL TO NOVAVAX]

Dear Mr. Erck,

I greatly appreciate Gregory Glenn serving on the ACTIV vaccines working group as a representative for Novavax. We have lots of activity across our ACTIV working groups moving at rapid speed. ACTIV (Accelerating COVID-19 Therapeutic Interventions and Vaccines) has a leadership team that meets once a month to discuss progress and we typically invite the CEO's of the biotech companies to join. It would be great to have you join future leadership meetings to represent Novavax as a partner.

Please let me know if you would be able to join our leadership team and David Wholley, cc'd who manages the ACTIV partnership will ensure you receive the meeting invite for our next meeting scheduled for Wednesday, July 29, 2:30-4:00pm.

Thanks,
Francis

Francis Collins M.D., Ph.D.
NIH Director

COLL0000015556-2517223

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 2/5/2021 9:11:52 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: FW: In case you have not seen
Attachments: Opinion _ Vaccines alone won't solve the pandemic. Here are 3 other things we must do. - The Washington Post.pdf

Hi Francis,

The attached op ed from the Post was just sent to Joe by one of our Preclinical WG members. Once again, ACTIV is being seriously and very publicly dissed, and this time by our 'friends' on the Biden transition team. I am personally distressed and disheartened. I am sure a lot of other folks involved with ACTIV will feel the same.

I believe we have to do a better job of telling our story, and we need to do it soon. While the authors make many good and helpful points, they are mostly wrong about the achievements of NIH in therapeutics. The antidote is hard facts and data.

- Once the next version of the ACTIV-2 protocol launches (expecting first patient in this weekend) ACTIV will have either tested or have in testing 15 (yes, fifteen) different agents, alone or in combination, for COVID-19. (In ACTIV-associated trials, NIH will have tested an additional 6 agents, plus convalescent plasma and IVIG).
- These drugs span the spectrum of treatments that address both the virus and its symptoms: immune modulators, mAbs, antivirals, anti-inflammatory drugs, and antithrombotics. (Borio et. al. totally ignore the antithrombotics, including the very significant results from ACTIV-4a on therapeutic doses of heparin last week.)
- The list also includes non-injectable formulations of antivirals, including an inhaled interferon-beta. More will be launched over the next few months.
- A number of other drugs have been judged to be already in effective trials funded by the private sector, and were therefore not appropriate candidates for government funding: Kaletra (AbbVie), EIDD-2801 (Merck), Icatibant, Ruzuprofatib, and Apremilast (I-SPY Covid trial, funded by OWS), fluvoxamine (Wash U./private philanthropy).
- We agree that nationwide (and probably globally), our clinical trial infrastructure, was simply not set up to do trials during a pandemic—we see the exhaustion on the faces of the nurses and clinicians who attend calls with our ACTIV trial teams. While this needs to be addressed in preparation for the next pandemic, the current lack of resources is a strong argument in support of a core principle of ACTIV: that we choose the best, most promising treatments to test using these limited available resources, with appropriate rigor.
- This means that up until now, some of the cheap, broadly available generics have not been tested despite their allure: the data supporting their efficacy has been insufficiently compelling to put them ahead of testing other more promising medications. NIH has indeed tested some of these (the "Canadian" trial of colchicine was co-funded by NHLBI), but we agree it is time to consider a rapid, pragmatic trial that could provide more conclusive testing of some of these agents. We are designing such a trial to be part of ACTIV.
- We are delighted to hear the Biden administration is proposing an additional investment of billions of dollars in COVID-19 research over the next several years. It is badly needed if we are to stay ahead of this virus and its mutations, and we are avidly cheering the arrival of this investment from the sidelines.

I do not know if the 60 Minutes or New Yorker pieces will happen soon enough or be able to include specific illustrations of the key datapoints (like the graphic version NIH is preparing of the table FNIH sent over). I do think something in short order in the Washington Post may be a good idea, but I leave that to the professionals.

Sorry to share my frustration. I hope this helps in inspiring a proactive, constructive response.

David

From: Menetski, Joseph (FNIH) [T] <(b) (6)>
Sent: Friday, February 5, 2021 11:56 AM
To: Wholley, David (FNIH) [T] <(b) (6)>
Subject: RE: In case you have not seen

FYI

From: Wholley, David (FNIH) [T] <(b) (6)>
Sent: Friday, February 5, 2021 11:41 AM
To: Menetski, Joseph (FNIH) [T] <(b) (6)>
Subject: RE: In case you have not seen

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From: Menetski, Joseph (FNIH) [T] <(b) (6)>
Sent: Friday, February 5, 2021 11:38 AM
To: Wholley, David (FNIH) [T] <(b) (6)>; Freire, Maria (FNIH) [T] <(b) (6)>
Subject: FW: In case you have not seen

Hmmm

From: Prabha Fernandes <(b) (6)>
Sent: Friday, February 5, 2021 10:21 AM
To: Menetski, Joseph (FNIH) [T] <(b) (6)>
Subject: In case you have not seen

<https://www.washingtonpost.com/opinions/2021/02/05/vaccines-alone-wont-solve-pandemic-here-are-3-other-things-we-must-do/>

From: Bharucha_David [(b) (6)]
Sent: 10/19/2020 1:52:39 PM
To: Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Atkinson, Jane (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0e3e449583b40e0b5bdfccfda71ced-jatkinso]; Chang, Soju (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99b3263e72a94bfa9ded3f82c4dae59c-changsoju]; (b) (6) [(b) (6) 'Gavin, Brian' [(b) (6) 'Sadeh, Jonathan' [(b) (6) 'Melsheimer, Rich [CNTNL]' [(b) (6) 'Beumont-Mauviel, Maria [JRDUS]' [(b) (6) Ferguson_William [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; 'LaVange, Lisa M' [lisa. (b) (6) Gardner, Bobbi (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3dd21d20185e4e46a20a6eb89c314580-gardnerbw]; 'Sandeep Menon' [(b) (6) 'Yong, Florence H' [(b) (6) 'Trank, Christina' (b) (6) Moyo_Vusi [(b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; 'Kimmel, Bridget [JRDUS' [(b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Marti, Emily (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=970fb6ea63944699aa433fb034a0f63f-carlsone]; Eisnor, Derek (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae393740634d4ec9954494c0c2ef669a-Derek.Eisno]; (b) (6) [(b) (6) Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Mason, Robin (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77156b112de94c439dbccb6894954618-Robin.Mason]; O'Sullivan_Alexandra [(b) (6) Waldron_Kathleen [(b) (6) 'Montgomery, Stephanie' [(b) (6) O'Sullivan_Alexandra [(b) (6) Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]; Neta Nelson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3d10b8fd5dff411eb1d6f8f4892e27e3-nnelson.tec]; Butler, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4782eaa72024479197826e3d71d5584c-sbutler.tec]; Daniel Benjamin Jr, M.D., Ph.D. [(b) (6) Theresa Jasion [(b) (6) Molina, Daniel [(b) (6) Rose Beci [(b) (6) Lind, Brian (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=486ebcc6ebe34d08a691e66632ed5005-lindbj]; Mason, Robin (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77156b112de94c439dbccb6894954618-Robin.Mason]; O'rourke, Anna (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a43de8d7c474c538615405753ccfb6c-Anna.O_rour]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Lori Hudson, Ph.D.

[(b) (6) "Huyen Cao" < (b) (6) ["Huyen Cao" < (b) (6) Huyen Cao (b) (6) Brody, Betty (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecad8c87c49d4f018bd2530beaf4a30d-Betty.Brody]; Chiang, Anna (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa42127fa32b4d0fa0ccce5799cf419f-Anna.Chiang]; Schmidt, Jeffrey (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3431da5ab88f4204858d4c6fe19aaa7a-Jeffrey.Sch]

Subject: RE: 1st ACTIV-1 patient has been randomized

Flag: Follow up

Congratulations and thank you to all,
David

David B. Bharucha, MD, PhD, FACC
Vice President, Clinical Development, R&D

abbvie

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Office: (b) (6)

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From: Proshan, Michael (NIH/NIAID) [E] < (b) (6) >

Sent: Monday, October 19, 2020 8:19 AM

To: Bozzette, Sam (NIH/NCATS) [E] < (b) (6) > Boucher, Cynthia (NIH/NCATS) [E]

< (b) (6) > Atkinson, Jane (NIH/NCATS) [E] < (b) (6) > Chang, Soju (NIH/NCATS) [E]

< (b) (6) > ' (b) (6) < (b) (6) > 'Gavin, Brian' < (b) (6) >

'Sadeh, Jonathan' < (b) (6) > 'Melsheimer, Rich [CNTNL]' < (b) (6) > 'Beumont-

Mauviel, Maria [JRDUS]' < (b) (6) > Bharucha_David < (b) (6) >

Ferguson_William < (b) (6) > Eric Hughes < (b) (6) > Read, Sarah

(NIH/NIAID) [E] < (b) (6) > 'LaVange, Lisa M' < (b) (6) > Gardner, Bobbi (NIH/NCATS) [E]

< (b) (6) > 'Sandeep Menon' < (b) (6) > 'Yong, Florence H'

< (b) (6) > 'Trank, Christina' < (b) (6) > Moyo_Vusi

< (b) (6) > Collins, Francis (NIH/OD) [E] < (b) (6) > 'Kimmel, Bridget [JRDUS]

< (b) (6) > Adam, Stacey (FNIH) [T] < (b) (6) > Marti, Emily (NIH/NCATS) [E]

< (b) (6) > Eisnor, Derek (OS/ASPR/BARDA) < (b) (6) > ' (b) (6) >

< (b) (6) > Austin, Christopher (NIH/NCATS) [E] < (b) (6) > Collins, Francis (NIH/OD) [E]

< (b) (6) > Woodcock, Janet (FDA/CDER) < (b) (6) > Mason, Robin (OS/ASPR/BARDA)

< (b) (6) >

Cc: 'Montgomery, Stephanie' < (b) (6) > O'Sullivan_Alexandra

< (b) (6) > Stock, Thomas (HHS/IOS) < (b) (6) > Neta Nelson

< (b) (6) > Butler, Sandy < (b) (6) > Daniel Benjamin Jr, M.D., Ph.D.

< (b) (6) > Theresa Jasion < (b) (6) > Molina, Daniel < (b) (6) >

Rose Beci < (b) (6) > Lind, Brian (NIH/NCATS) [E] < (b) (6) > Mason, Robin (OS/ASPR/BARDA)

< (b) (6) > O'rourke, Anna (OS/ASPR/BARDA) (CTR) < Anna. (b) (6) > Austin, Christopher

(NIH/NCATS) [E] < (b) (6) > Lori Hudson, Ph.D. < (b) (6) > "Huyen Cao"

< (b) (6) > <"Huyen Cao" < (b) (6) > Huyen Cao < (b) (6) > Brody, Betty

COLL0000014012-2517226

(OS/ASPR/BARDA) < (b) (6) Chiang, Anna (OS/ASPR/BARDA) < (b) (6) Schmidt, Jeffrey
(OS/ASPR/BARDA) < (b) (6)

Subject: RE: 1st ACTIV-1 patient has been randomized

Fantastic! Way to go.

Mike.

From: Bozzette, Sam (NIH/NCATS) [E] < (b) (6) >

Sent: Friday, October 16, 2020 4:48 PM

To: Boucher, Cynthia (NIH/NCATS) [E] < (b) (6) > Atkinson, Jane (NIH/NCATS) [E]

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(b) (6) 'Gavin, Brian' (b) (6) > 'Sadeh, Jonathan' (b) (6) >;
'Melsheimer, Rich [CNTNL]' (b) (6) > 'Beumont-Mauviel, Maria [JRDUS]' (b) (6) >;
'Bharucha_David' (b) (6) > 'Ferguson_William' (b) (6) >; Eric Hughes
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(b) (6) >; Proschan, Michael (NIH/NIAID) [E] (b) (6) >; Gardner, Bobbi (NIH/NCATS) [E]
(b) (6) >; 'Sandeep Menon' < (b) (6) > 'Yong, Florence H'
(b) (6) >; 'Trank, Christina' (b) (6) >; 'Moyo, Vusi'
(b) (6) >; Collins, Francis (NIH/OD) [E] (b) (6) >; 'Kimmel, Bridget [JRDUS]
(b) (6) Adam, Stacey (FNIH) [T] (b) (6) > Marti, Emily (NIH/NCATS) [E]
(b) (6) >; Eisnor, Derek (OS/ASPR/BARDA) < (b) (6) > (b) (6)
(b) (6) > Austin, Christopher (NIH/NCATS) [E] (b) (6) >; Collins, Francis (NIH/OD) [E]
< (b) (6) > Woodcock, Janet (FDA/CDER) (b) (6) >; Mason, Robin (OS/ASPR/BARDA)
<Robin.M (b) (6) >

Cc: 'Montgomery, Stephanie' (b) (6) >; O'Sullivan_Alexandra

(b) (6) >; Stock, Thomas (HHS/IOS) (b) (6) >; Neta Nelson
(b) (6) Butler, Sandy (b) (6) >; Daniel Benjamin Jr, M.D., Ph.D.
(b) (6) Theresa Jasion (b) (6) >; Molina, Daniel < (b) (6) >
Rose Beci < (b) (6) >; Lind, Brian (NIH/NCATS) [E] (b) (6) >; Mason, Robin (OS/ASPR/BARDA)
(b) (6) >; O'rourke, Anna (OS/ASPR/BARDA) (CTR) (b) (6) > Austin, Christopher
(NIH/NCATS) [E] (b) (6) >; Lori Hudson, Ph.D. (b) (6) >; "Huyen Cao"
(b) (6) <"Huyen Cao" (b) (6) > Huyen Cao (b) (6) >om>; Brody, Betty
(OS/ASPR/BARDA) (b) (6) >; Chiang, Anna (OS/ASPR/BARDA) (b) (6) >; Schmidt, Jeffrey
(OS/ASPR/BARDA) (b) (6) >

Subject: 1st ACTIV-1 patient has been randomized

Hello:

The first patient has been randomized into ACTIV-1. Congratulations to all, especially Bill Powderly, Jane O'Halloran, and the rest of the Wash U team.

Happy weekend to all!

Sam B

Sam Bozzette, MD, PhD

Chief Medical Officer

Immediate Office of the Director

National Center for Advancing Translational Sciences

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From: Pangalos, Mene [(b) (6)]
Sent: 6/5/2020 10:55:10 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Esser, Mark [(b) (6)] Villafana, Tonya [(b) (6)]
Subject: RE: combinatorics and monoclonal Abs - Data Shared In Confidence

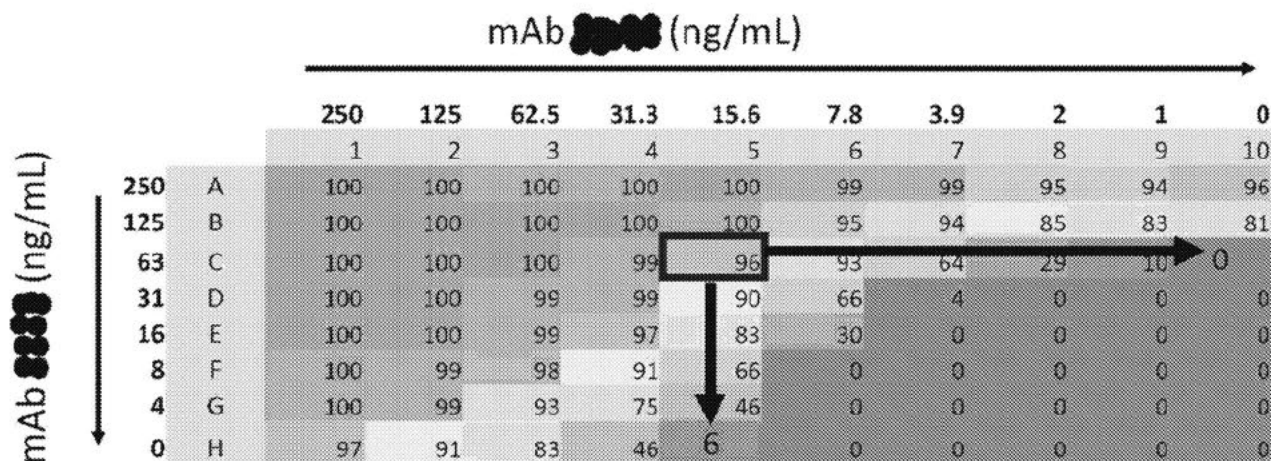
Francis,

We do these assays ourselves and with collaborators... they are often done in oncology as I am sure you know. This is data from two of our mAbs that demonstrated what we are looking for.

Please do not share this data set as is yet to be published and I am sharing in confidence but hopefully gives you a sense of what we do and what we hope to observe. Our cocktail moving forward will take the two mAbs with the best synergistic effect in neut assays into the clinic (which we have in fact already selected).

These sorts of assays could be used to test a variety of antibodies from different sources to find combinations that work and will be important if resistance emerges.

Mene



Sir Menelas N Pangalos PhD FRSB FMedSci
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From: Collins, Francis (NIH/OD) [E] < (b) (6) >

Sent: 05 June 2020 02:26

To: Pangalos, Mene < (b) (6) >

COLL0000017510-2517247

Cc: Wholley, David (FNIH) [T] < (b) (6)>

Subject: combinatorics and monoclonal Abs

Hi Mene,

I think I heard you say something during the ACTIV call yesterday about ways to optimize the choice of mAbs that would be synergistic. For the upcoming inpatient and outpatient trials of mAbs against SARS-CoV-2, it would be great to have available a preclinical in vitro assay that could predict that kind of synergy in vivo. Do you have an approach that you or someone on your staff would be willing to tell me about?

Best, Francis

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Sent: 1/13/2021 3:55:22 PM
To: (b) (6) (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m; (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; (b) (6) com; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; (b) (6) Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T]

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim,
Elizabeth [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi
Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li
[(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
[(b) (6) Dave Frankowski [(b) (6) antoinette_baric
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb6b844cf]; Lowy,
Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nancy Haigwood
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188];
Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Mason, Stephen
[(b) (6) Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; (b) (6) Lumsden, Joanne (NIH/NCATS) [C]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Lloyd
[(b) (6)

Subject: RE: ACTIV Preclinical full working group

Attachments: 6-month consequences of COVID-19 in patients discharged from hospital_ a cohort study _ Elsevier Enhanced Reader.pdf

Dear all,

Thought you might be interested in this article on COVID-19 sequelae.

Does anyone know of other reports like this? It could be important to incorporate this in our thoughts for therapeutics going forward.

Best regards,
Joe

From: (b) (6) [(b) (6)]
Sent: 6/10/2020 8:42:37 AM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]
Subject: Fwd: Agenda and materials for the Protective Immune Responses Sub-Group meeting
Attachments: image001.jpg; ATT00001.htm; image002.jpg; ATT00002.htm; image003.jpg; ATT00003.htm; image004.jpg; ATT00004.htm; Assay WG Tracker _ Updated 6-4.xlsx; ATT00005.htm

Hi Chris,

Forwarding the information for the vaccines subgroup meeting taking place at 2:30pm today and follow up conversations next week with Janet on USG assay development— thought others particularly NCATS may want to participate and not currently represented on the protective immune response SG.

Cc'ing Cliff for awareness — seems there are contacts for NIAID.

Best,
Ashley

Begin forwarded message:

From: "Santos, Michael (FNIH) [T]" (b) (6)
Date: June 9, 2020 at 10:59:53 PM EDT
To: " (b) (6) " < (b) (6) >
 < (b) (6) > "Gruber, Marion (FDA/CBER)"
 (b) (6) >, "Marks, Peter (FDA/CBER)" (b) (6)
 (b) (6) " (b) (6) < (b) (6) "Arvin, Ann"
 < (b) (6) Nelson Michael < (b) (6) "Bett, Andrew J"
 (b) (6) "Gilbert PhD, Peter B" (b) (6) >, "Kathleen Neuzil"
 < (b) (6) "Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA)"
 (b) (6) >, "Thornburg, Natalie (CDC/DDID/NCIRD/DVD)" < (b) (6)
 Greg Glenn (b) (6) Cavaleri Marco (b) (6) , "Kelly, Beth"
 (b) (6) >
Cc: "Tolman, Brett" ((b) (6) < (b) (6) >
 (b) (6) , Jeneffer Haynes < (b) (6) >,
 "Menetski, Joseph (FNIH) [T]" (b) (6) >, "Alvarez, Rosa Maria" < (b) (6) >,
 "Wholley, David (FNIH) [T]" (b) (6) >, "Parker, Ashley (NIH/OD) [E]"
 (b) (6) Brian Rosen (b) (6) >, Cheryl Keach (b) (6) >
Subject: Agenda and materials for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting at 2:30pm ET (11:30am PT / 6:30pm CEST).

Last week we were fortunate to have Marco Cavaleri present and lead a discussion on EMA regulatory pathways. Development of a table of those pathways analogous to the table developed for FDA pathways is underway.

At this meeting we will return to the topics from two weeks ago: (1) reaching out to collect information on potential signals of human immunity and (2) inter-comparability of immunogenicity assays and centralized labs.

Since that meeting Ann and Mark Davis discussed the first topic, and reached out to Dan Rotrosen (Director of the Division of Allergy, Immunology, and Transplantation at NIAID). He is unfortunately unable to join this meeting, but we will discuss the categories of information we would like to collect and the potential process for doing so.

On the second topic, we reached out to Janet Lathey (NIAID) and Ashley Smith (BARDA), who co-lead a USG working group on assay development. They kindly provided the attached draft list of assays under development through USG mechanisms. Janet will join our meeting next week to discuss the assays and engagement by vaccine developers with the labs running them.

Please let us know if you have any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Wednesday, June 3, 2020 11:30 PM
Subject: Notes from yesterday's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting, and particular thanks to Marco for the excellent presentation and discussion.

Meeting notes are attached, with the meeting materials are embedded. The key action item is developing a table of EMA pathways analogous to the one that we previously developed with Marion's input and review for FDA pathways.

Please reach out with any additions or edits to the notes, questions, or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Monday, June 1, 2020 1:04 PM
Subject: Agenda and materials for the Protective Immune Responses Sub-Group meeting tomorrow (Tuesday)

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting tomorrow (Tuesday) at 8am ET (5am PT / 2pm CEST). We are very sorry for the extremely early start PT.

The main agenda item is to discuss EMA and member state regulatory pathways to vaccine use and approval. Marco will lead the discussion. He previously shared a set of presentation slides (re-attached here). We are also re-attaching the table on FDA pathways that we circulated previously.

Please let us know if you have any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Thursday, May 28, 2020 12:57 PM
Subject: Notes and next steps from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting. Notes are attached.

There were two key areas for next steps that we identified in the meeting:

- Potential signals of human immunity:
 - Develop specifics of what we are looking for from immunology research
 - Ask the WG and other contacts for suggestions of researchers/organizations worth reaching out to
 - Reach out and collect information and contacts to engage with the WG (in presentations or other formats)
- Inter-comparability of immunogenicity assays / centralized labs
 - Reach out to NIAID to learn more about planned centralized lab capabilities and timing

Ann kindly followed up with an initial set of recommendations for the first area. We'll be following up to develop the list of information that we'd like to gather and to discuss how to prioritize whom we reach out to. We'll reach out to NIAID and report back on the second area.

We think these topics will form the basis for future discussions, but we are also trying to schedule a meeting for a time when we can have a discussion about the EMA regulatory pathways with Marco, to complement the conversations we have had on FDA pathways. We hope to have an invite for that out soon.

As always, please reach out with any additional input on the notes, questions, or suggestions for future directions for this group.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 11:42 PM
Subject: Agenda for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to today's (Wednesday) meeting, at 9am ET (6am PT / 3pm CEST).

Since our last meeting, Marco kindly shared the attached document on EMA and member state regulatory pathways for vaccine use and approval. Unfortunately Marco won't be able to join this meeting, but has offered to discuss the EMA pathways at a future meeting.

Our recent meetings have focused primarily on understanding regulatory pathways for vaccine use and approval, and the types of evidence that factor into regulatory decisions for different pathways, with two presentations on upcoming sources of evidence (NIAID NHP challenge studies using sera/IgG/mAbs and CDC immunological studies). A key goal of this group is to facilitate vaccine developers to generate evidence that can support evaluation of vaccine efficacy. For today's meeting, we plan to discuss the different categories of evidence and identify priorities for ACTIV to engage to be supportive.

We look forward to the discussion. If you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 12:19 AM
Subject: Notes from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached notes and materials from our meeting last week. Thanks again to Donna and Natalie for presenting, and as always to Marion for her contributions to the regulatory pathways during the meeting and subsequently.

We will be in touch again soon regarding this week's meeting. Feel free to reach out any time with questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 19, 2020 8:56 AM
Subject: Agenda and Materials for today's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached two documents for today's Protective Immune Responses Sub-Group meeting (2pm ET / 11am PT / 8pm CEST):

- An updated table of pathways to vaccine use
- Notes from the last Sub-Group meeting (with my apologies for the delay)

For today's meeting, the agenda items are:

- Discussion of the updated pathways table and next steps
- An overview of the CDC's serology activities by Natalie

We're looking forward to the discussion today. As always, if you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health
(b) (6) | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 6/8/2020 8:57:42 PM
To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
CC: Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: another member for ACTIV Clinical Trial Capacity Working Group

Hi Karen,

I hope you are well and had a great weekend!

I think FNIH has developed a process for obtaining permissions for future participants which includes asking via email after they've indicated participation with the POC – cc'ing your very own Cheryl to confirm and who's been super helpful.

Also cc'ing Renate and Lauren Brodd for awareness only. Lauren will be working closely with me and Renate, NIH OD to assist with keeping the NIH website for ACTIV up to date.

Thanks again,
Ashley

From: Tountas, Karen (FNIH) [T] <(b) (6)>
Sent: Monday, June 8, 2020 4:40 PM
To: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Cc: Meltzer, Abbey (FNIH) [T] <(b) (6)>
Subject: another member for ACTIV Clinical Trial Capacity Working Group

Hi Ashley,

I hope you had a nice weekend. Please note that the CT Capacity Working Group has a new member from AstraZeneca.

- Therese Takas
Director, Clinical Operations
AstraZeneca

Her email contact to obtain permission to list her on the NIH ACTIV website is therese.takas@astrazeneca.com

Many thanks!
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health
(b) (6) | fnihi.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Magbie-Robinson, Kim (NIH/OD) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=74A5B9CEA10B4F919D9DB20C8AAEC3E7-MAGBIEROBIN]
Sent: 10/27/2020 5:41:35 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: ACTIV Preclinical full working group

Thanks Ashley!

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Tuesday, October 27, 2020 1:41 PM
To: Wolinetz, Carrie (NIH/OD) [E] <(b) (6)>
Cc: Magbie-Robinson, Kim (NIH/OD) [C] <(b) (6)>
Subject: FW: ACTIV Preclinical full working group

Just further confirming the ACTIV EC will take place next week, 11/4! Other ACTIV meetings will be moved.

From: Menetski, Joseph (FNIH) [T] <(b) (6)>
Sent: Tuesday, October 27, 2020 12:13 PM
To: (b) (6); Hild, Sheri (NIH/OD) [E] (b) (6)
(b) (6); Baric, Ralph (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E]
(b) (6) Colvis, Christine (NIH/NCATS) [E] (b) (6) Hewitt, Judith (NIH/NIAID)
[E] (b) (6) Deming, Damon (FDA/CDER) (b) (6);
(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] <(b) (6)>
(b) (6); Adams, Peter (OS/ASPR/BARDA) (b) (6); Rao, Srinivas
(b) (6) Qashu, Felicia (NIH/OD) [E] (b) (6); Tomas Cihlar
(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) (b) (6)
Punturieri, Antonello (NIH/NHLBI) [E] (b) (6); Charette, Marc (NIH/NHLBI) [E]
<(b) (6); Fessel, Josh (NIH/NHLBI) [E] (b) (6)
Cc: Diamond, Michael (b) (6); Wholley, David (FNIH) [T] (b) (6); Austin, Christopher
(NIH/NCATS) [E] (b) (6); Melencio, Cheryl (FNIH) [T] (b) (6); Colvis, Christine
(NIH/NCATS) [E] (b) (6) Desrosiers, Betsy <(b) (6)>; Eric Hughes
(b) (6); Jansen, Kathrin (b) (6); Kurilla, Michael (NIH/NCATS) [E]
<(b) (6)>; Lowy, Douglas (NCI) (b) (6) Read, Sarah (NIH/NIAID) [E] <(b) (6) gov>;
Tountas, Karen (FNIH) [T] (b) (6); Santos, Michael (FNIH) [T] <(b) (6)>; Adam, Stacey (FNIH) [T]
(b) (6); James, Stephanie (FNIH) [T] <(b) (6)>; Alvarez, Rosa Maria <(b) (6)>
Kim, Elizabeth <(b) (6)>; btolman (b) (6); Wachtel, Jonathan (b) (6)
Prabhavathi Fernandes <(b) (6)>; Rose Li (b) (6); Dana Carluccio
(b) (6); Lagos, Enrique (NIH/NCATS) [E] <(b) (6)>; Jonson, Samantha
(NIH/NCATS) [E] <(b) (6)>; Gonzalez, Nina <(b) (6)>; Simon, Dina (NIH/OD) [C]
(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] <(b) (6)>; Rodriguez, Robin D
>; Dave Frankowski (b) (6); Baric, Toni C
(b) (6); Lowy, Douglas (NIH/NCI) [E] (b) (6); Florence, Clint (NIH/NIAID) [E]
(b) (6); Nancy Haigwood (b) (6); Stratton, Benjamin (b) (6);
Gadbois, Ellen (NIH/OD) [E] (b) (6); Anderson, James (NIH/OD) [E] (b) (6);
Hawk, Harrison (b) (6); Mason, Stephen (b) (6);
(b) (6); Connelly, Sarah (b) (6)
Subject: ACTIV Preclinical full working group

Dear Preclinical working group,

Next week's ACTIV EC meeting (Nov 4th) has been scheduled on top of our full working group meeting. It is important for us to talk, especially after the EC meeting, so I was hoping we can move this to either:

Option A: 11-12 Wed, Nov 4, 2020

Option B: 10-11 Thur, Nov 5, 2020

Can you please let me know which of these options work for you. I will move the meeting to the most popular option.

Best regards,

Joe

Joseph P. Menetski Ph.D.

Associate Vice President, Research Partnerships

Foundation for the National Institutes of Health

(b) (6) | fnih.org

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 6/4/2020 9:49:48 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b224466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: A couple of additional notes from today's conversation

Francis:

Sure hope your task force/OWS meeting with Moncef et. al. went well—anxious to hear results. A few additional fyi's/requests to consider:

- 1) Jacqueline Kirchner of Gates Foundation (ex-Amgen, knows her stuff) approached Stacey and her co-chairs to say that Gates would be interested in combinatoric testing of mAbs. They have 2 in vitro tests (pseudo and live virus) as well as a Syrian Golden hamster model they are developing and are in discussion with several companies. Of course that will mean they want "in" on our testing platform, strategies, and results, but seems worth a conversation. Shall we arrange it, and whom with?
- 2) I think I ran to ground the source of the request that was brought up from Hilary Marston to have someone from ACTIV brief Janet, and it involves an issue you and Cliff may want to think about helping out on. We think the request came from Janet via Kevin Bugin, and involves Janet's repeated (and apparently frustrated) requests to get clarity from NIAID on the choice of CRO to run the mAB trials (or perhaps just the inpatient trial?). To their credit, DAIDS and DCR are doing their utmost to run the outpatient and inpatient mAb trials on a single unified infrastructure: single DSMB, common clinical data capture and management platform, and a common CRO. The problem is that the CRO that they have chosen is PPD, and PPD is apparently the CRO chosen for all the NIAID vaccine trials as well. Janet and her team are worried that the choice of PPD for the mAbs will look biased, and that PPD may not really have the capacity to do everything. They would prefer to rapidly RFP this, include some of the BARDA CROs on the RFP, and move forward from there. We have been trying to use the ACTIV WG structure to arrange a call on this, but the DAIDS folks have balked, saying "we've got this, we'll talk about it later" (in other words "please go away"). Our guess is Janet is frustrated by this and is trying to find another route through Hilary. Taking full account of your statement on today's call that we need to support (and communicate well with) Janet, is this something you can help her with?

Thanks, David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

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APAR0000001294-2517337

From: Gonzalez, Nina [(b) (6)]
Sent: 5/29/2020 7:45:38 PM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Elsaid, Olivia [(b) (6)]
Subject: RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30

All –

Deloitte is available for any slide harmonization this evening – just let Olivia and I know what you need.

Thanks,

Nina

From: Freire, Maria (FNIH) [T] < (b) (6) >
Sent: Friday, May 29, 2020 3:36 PM
To: Wholley, David (FNIH) [T] < (b) (6) > Collins, Francis (NIH/OD) [E] < (b) (6) >
Cc: Adam, Stacey (FNIH) [T] < (b) (6) > Gonzalez, Nina < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) >
Subject: [EXT] RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Yes, I will send it to Nina.

From: Wholley, David (FNIH) [T] (b) (6) >
Sent: Friday, May 29, 2020 3:33 PM
To: Collins, Francis (NIH/OD) [E] (b) (6) >
Cc: Adam, Stacey (FNIH) [T] (b) (6) >; Freire, Maria (FNIH) [T] (b) (6) >; Gonzalez, Nina (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) >
Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

By copy to Nina Gonzalez, I am asking formally if that is OK. We are fine with that of course. Ashley and Maria are corresponding on a slide that might fit for #1.

From: Collins, Francis (NIH/OD) [E] (b) (6) >
Sent: Friday, May 29, 2020 3:30 PM
To: Wholley, David (FNIH) [T] (b) (6) >
Cc: Adam, Stacey (FNIH) [T] (b) (6) >; Freire, Maria (FNIH) [T] (b) (6) >; Gonzalez, Nina (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) >
Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi David,

Sorry, had an e-mail crash and am just now seeing this – it's a good thing you didn't wait for me! The outline looks good, I'll wait for the Deloitte versions. I don't have a slide that fits #1. NHLBI (Amy Patterson) is working on things for me by COB on anticoagulants. If I need to harmonize, is Deloitte available this evening?

FC

From: Wholley, David (FNIH) [T] (b) (6)
Sent: Friday, May 29, 2020 1:59 PM
To: Collins, Francis (NIH/OD) [E] (b) (6) >
Cc: Adam, Stacey (FNIH) [T] (b) (6) >; Freire, Maria (FNIH) [T] (b) (6) >; Gonzalez, Nina (b) (6) >; Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis:

Here is the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a **portfolio** approach to addressing the dramatic health and economic challenges posed by the pandemic, with harmonized efforts that address both disease etiology and symptomology.
 - ACTIV Baricitinib (ACTT2, sponsored by NIAID) – in progress
 - ACTIV hiVIG (sponsored by NIAID) – in progress
 - ACTIV-1 – Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) – (Phase III) – ready to launch late June
 - ACTIV-2* – Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
 - ACTIV-3* – Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
 - ACTIV-4 – Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually, Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS "Master" Network) – (Phase II/III) – projected launch late June
 - ACTIV-5 – De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) – similar design to the mAb protocols, networks/sites/agents in discussions now – projected launch August (*if needed; i.e. if agents are not incorporated into mAb protocols*)
 - * current priority

[for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base
- Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
- Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)
[Key Criteria for Scoring (slide 15 from 5/20) can go to backup
- Prioritization and Protocol Design: Who is Involved – two-box slide containing names and affiliations of those involved in the Prioritization and MP Subgroups (quality folks!)
- ACTIV-1 Protocol for immunomodulators
 - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)

- 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
- All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials = high POS
- Phase III master protocol design for ACTIV-1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)
- Companies have agreed to share data + common control arm + common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
- Protocol is 80% complete
 - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
 - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)
 - All three companies have written their sections of the protocols, which are being merged into the master design
- Working with OWS/BARDA on choice of CRO to run the trial; (b) (5)
- “ACTIV-4” Protocol for anticoagulants
 - Need bullets from NHBLI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS “network of networks” with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley
 Senior Vice-President, Research Partnerships
 Foundation for the National Institutes of Health

(b) (6)

fnih.org

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v.E.1

APAR0000001343-2517357

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 6/21/2020 7:05:57 PM
To: (b) (6) (b) (6) (b) (6) (b) (6)
Gruber, Marion (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebf7a8eb8dd541b2883a966ea5afd809-GRUBER.fda]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; (b) (6)
(b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta]; Nelson Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; Bett, Andrew J [(b) (6) Gilbert PhD, Peter B [(b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.com]; Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA) [(b) (6) Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Greg Glenn [(b) (6) Cavaleri Marco [(b) (6) Kelly, Beth [(b) (6)
CC: Tolman, Brett [(b) (6) (b) (6) (b) (6)
(b) (6) Jeneffer Haynes [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Brian Rosen [(b) (6) Cheryl Keech [(b) (6) Lathey, Janet (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=313a30054ad2477c8580ae7516b5f77c-latheyjl]; Stratton, Benjamin [(b) (6)
Subject: Notes from the Protective Immune Responses Sub-Group meeting
Attachments: 2020-06-18 Protective Immune Responses Sub-Group meeting Notes.docx

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in our last meeting, and particular thanks to Janet for joining us.

Meeting notes are attached, with the meeting materials are embedded.

As always, please reach out with any additions or edits to the notes, questions, or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Wednesday, June 17, 2020 9:33 PM
Subject: Agenda for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

APAR0000006176-2517364

We're looking forward to our meeting tomorrow (Thursday) at 1pm ET (10am PT / 7pm CEST).

We will continue our discussion from last week about assays. Janet Lathey (NIAID and co-lead of USG Assay Working Group) will kindly join the meeting to discuss the set of assays that the USG is supporting the development of (spreadsheet attached).

Best regards,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Saturday, June 13, 2020 8:37 PM
Subject: Notes from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in our last meeting.

Meeting notes are attached, with the meeting materials are embedded. Janet Lathey (NIAID and co-lead of USG Assay Working Group) plans to join our next meeting, when we will have the opportunity to continue to assess assay needs and availability.

As always, please reach out with any additions or edits to the notes, questions, or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, June 9, 2020 11:00 PM
Subject: Agenda and materials for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting at 2:30pm ET (11:30am PT / 6:30pm CEST).

Last week we were fortunate to have Marco Cavaleri present and lead a discussion on EMA regulatory pathways. Development of a table of those pathways analogous to the table developed for FDA pathways is underway.

At this meeting we will return to the topics from two weeks ago: (1) reaching out to collect information on potential signals of human immunity and (2) inter-comparability of immunogenicity assays and centralized labs.

Since that meeting Ann and Mark Davis discussed the first topic, and reached out to Dan Rotrosen (Director of the Division of Allergy, Immunology, and Transplantation at NIAID). He is unfortunately unable to join this meeting, but we will discuss the categories of information we would like to collect and the potential process for doing so.

On the second topic, we reached out to Janet Lathey (NIAID) and Ashley Smith (BARDA), who co-lead a USG working group on assay development. They kindly provided the attached draft list of assays under development through USG

mechanisms. Janet will join our meeting next week to discuss the assays and engagement by vaccine developers with the labs running them.

Please let us know if you have any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Wednesday, June 3, 2020 11:30 PM
Subject: Notes from yesterday's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting, and particular thanks to Marco for the excellent presentation and discussion.

Meeting notes are attached, with the meeting materials are embedded. The key action item is developing a table of EMA pathways analogous to the one that we previously developed with Marion's input and review for FDA pathways.

Please reach out with any additions or edits to the notes, questions, or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Monday, June 1, 2020 1:04 PM
Subject: Agenda and materials for the Protective Immune Responses Sub-Group meeting tomorrow (Tuesday)

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting tomorrow (Tuesday) at 8am ET (5am PT / 2pm CEST). We are very sorry for the extremely early start PT.

The main agenda item is to discuss EMA and member state regulatory pathways to vaccine use and approval. Marco will lead the discussion. He previously shared a set of presentation slides (re-attached here). We are also re-attaching the table on FDA pathways that we circulated previously.

Please let us know if you have any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Thursday, May 28, 2020 12:57 PM
Subject: Notes and next steps from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting. Notes are attached.

There were two key areas for next steps that we identified in the meeting:

- Potential signals of human immunity:
 - Develop specifics of what we are looking for from immunology research
 - Ask the WG and other contacts for suggestions of researchers/organizations worth reaching out to
 - Reach out and collect information and contacts to engage with the WG (in presentations or other formats)
- Inter-comparability of immunogenicity assays / centralized labs
 - Reach out to NIAID to learn more about planned centralized lab capabilities and timing

Ann kindly followed up with an initial set of recommendations for the first area. We'll be following up to develop the list of information that we'd like to gather and to discuss how to prioritize whom we reach out to. We'll reach out to NIAID and report back on the second area.

We think these topics will form the basis for future discussions, but we are also trying to schedule a meeting for a time when we can have a discussion about the EMA regulatory pathways with Marco, to complement the conversations we have had on FDA pathways. We hope to have an invite for that out soon.

As always, please reach out with any additional input on the notes, questions, or suggestions for future directions for this group.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 11:42 PM
Subject: Agenda for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to today's (Wednesday) meeting, at 9am ET (6am PT / 3pm CEST).

Since our last meeting, Marco kindly shared the attached document on EMA and member state regulatory pathways for vaccine use and approval. Unfortunately Marco won't be able to join this meeting, but has offered to discuss the EMA pathways at a future meeting.

Our recent meetings have focused primarily on understanding regulatory pathways for vaccine use and approval, and the types of evidence that factor into regulatory decisions for different pathways, with two presentations on upcoming sources of evidence (NIAID NHP challenge studies using sera/IgG/mAbs and CDC immunological studies). A key goal of this group is to facilitate vaccine developers to generate evidence that can support evaluation of vaccine efficacy. For today's meeting, we plan to discuss the different categories of evidence and identify priorities for ACTIV to engage to be supportive.

We look forward to the discussion. If you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 12:19 AM
Subject: Notes from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached notes and materials from our meeting last week. Thanks again to Donna and Natalie for presenting, and as always to Marion for her contributions to the regulatory pathways during the meeting and subsequently.

We will be in touch again soon regarding this week's meeting. Feel free to reach out any time with questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 19, 2020 8:56 AM
Subject: Agenda and Materials for today's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached two documents for today's Protective Immune Responses Sub-Group meeting (2pm ET / 11am PT / 8pm CEST):

- An updated table of pathways to vaccine use
- Notes from the last Sub-Group meeting (with my apologies for the delay)

For today's meeting, the agenda items are:

- Discussion of the updated pathways table and next steps
- An overview of the CDC's serology activities by Natalie

We're looking forward to the discussion today. As always, if you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health

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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/2/2020 9:33:06 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: Donor Funded Multi-Arm Adaptive Clinical Trial for COVID 19

Francis,
Stacey has reminded me that Judy Currier sits on the ACTIV TX-Clinical WG helping us to design the master protocol. She is also the head of the ATCG network for NIAID.

David

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Saturday, May 2, 2020 11:16 AM
To: Mazziotta, John M.D., Ph.D. <(b) (6)>
Cc: Wholley, David (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)> McManus, Ayanna (NIH/OD) [E] <(b) (6)>
Subject: RE: Donor Funded Multi-Arm Adaptive Clinical Trial for COVID 19

Hi John,

Many thanks for reaching out. I know Sean from the cancer immunotherapy programs, but wasn't aware of his efforts on COVID-19. Your outreach is incredibly timely. On April 3, NIH formed a rapid-action partnership with 16 pharmaceutical companies, the FDA, the CDC, and BARDA, to regularize what started out as a rather chaotic arrangement of small trials that might not meet the critical need for rapid initiation of rigorous trials. The partnership is called ACTIV (Accelerating COVID-19 Therapeutic Interventions and Vaccines) and in just one month has made major strides in prioritizing the next set of candidate therapeutics, designing master protocols, and developing a comprehensive picture of the clinical trial networks that need to be coordinated for effective therapeutic and vaccine trials. See <https://www.nih.gov/news-events/news-releases/nih-launch-public-private-partnership-speed-covid-19-vaccine-treatment-options> It would be terrific to have your California effort integrated into the ACTIV plan, and really unfortunate to have it go forward in a disconnected way.

I'd be glad to talk with you and Judy about this, and would want to include David Wholley and Stacey Adam of FNIH on the call, as they are doing the program management for this part of ACTIV. My calendar can be wrestled effectively by Gretchen or Ayanna.

Please let's make sure these efforts get effectively connected – this is no time for chaos!

Best, Francis

From: Mazziotta, John M.D., Ph.D. <(b) (6)>
Sent: Saturday, May 2, 2020 10:25 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Subject: Donor Funded Multi-Arm Adaptive Clinical Trial for COVID 19

Hi Francis,

It's been many years since we've spoken - back to the days of the Hereditary Disease Foundation in Santa Monica and Milton Wexler. I trust you're still in contact with Nancy. I've admired what you've accomplished at NIH.

I'm writing about an opportunity. Sean Parker (Napster, FaceBook, Parker Consortium for Cancer Immunotherapy, etc) has focused all his attention and substantial wealth on COVID 19. I've known Sean now for many years - self taught immunologist, extremely smart and usually highly focused. He's been working with Stanford and his own consortium people to establish this multi-arm, adaptive, trial. He wants to bring in UCLA and UCSF. He has other philanthropists that will support it and personally would start this project with ~\$20 million. I had a call with him and our UCLA experts, lead by Judy Currier last week and have had 2-3 more calls this week. I've been trying to have him do this through NIH and the FDA. The preliminary estimate is that 8,000 patient would be required and a mix of outpatient, inpatients and ICU patients. California numbers, especially outside of LA are low, and I've suggested including NY, Detroit, and other hot spots. All have agreed.

I know very little about clinical drug trials - I'm a neuroscientist who used imaging to study the human brain. That said, I trust Judy's judgement and she sees promise in this plan but also agrees it should be sanctioned, overseen and managed by NIH. I also know that the costs would quickly outpace the funding Sean and his colleagues would bring to the table.

So, would you be interested to have a brief call with me and Judy and, if productive, have a call with Sean? I think it would be worth a few minutes to hear about it.

Thanks - we're all busy but I wanted to try to make this something that could actually work.

John

John Mazziotta, M.D., Ph.D.
Vice Chancellor of UCLA Health Sciences
CEO UCLA Health
660 Charles Young Drive, South
Los Angeles, CA 90095

Phone: (b) (6)

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From: Hewitt, Judith (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2D0A7DADFCD42CBB4014D9B26AF30CC-JHEWITT]
Sent: 6/12/2020 2:55:07 PM
To: Young, John [(b) (6)] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
CC: Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Alvarez, Rosa [(b) (6)] Anderson, Annaliesa [(b) (6)] Baric, Ralph [(b) (6)]
[(b) (6)] Carter, Kara [(b) (6)] Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Cihlar, Tomas [(b) (6)]
Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [(b) (6)]
[(b) (6)] Diamond, Michael [(b) (6)] Duncan, Ken [(b) (6)] Fernandes, Prabhavathi [(b) (6)]
Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Florence, Clint (NIH/NIAID) [E] [(b) (6)]
[(b) (6)] Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gatto, Greg [(b) (6)]
Grobler, Jay [(b) (6)] Jonson, Samantha (NIH/NCATS) [E] [(b) (6)] Lutz, Cat [(b) (6)]
Nancy Haigwood [(b) (6)] Nestle, Frank [(b) (6)] Ottinger, Elizabeth (NIH/NCATS) [E] [(b) (6)]
Parker, Ashley (NIH/OD) [E] [(b) (6)] Payne, David [(b) (6)] Pitt, Louise [(b) (6)]
Punturieri, Antonello (NIH/NHLBI) [E] [(b) (6)] Qashu, Felicia (NIH/OD) [E] [(b) (6)]
Rao, Srinivas [(b) (6)] Rappaport, Jay [(b) (6)] Stegmeier, Frank [(b) (6)]
Subject: RE: FW: Agenda and materials for the Protective Immune Responses Sub-Group meeting

Just to be clear, these are government/govt contract funded assay development efforts, non-proprietary assays, and not the universe of assay development efforts. I do think it's a very nice table and would be great to post! We could consider copying some categories, although these immunoassays are used differently than drug screening assays.

From: Young, John < (b) (6) >
Sent: Friday, June 12, 2020 10:32 AM
To: Menetski, Joseph (FNIH) [T] < (b) (6) >
Cc: Adams, Peter (OS/ASPR/BARDA) < (b) (6) > Alvarez, Rosa < (b) (6) > Anderson, Annaliesa < (b) (6) > Baric, Ralph < (b) (6) > Carter, Kara < (b) (6) >
Charette, Marc (NIH/NHLBI) [E] < (b) (6) > Cihlar, Tomas < (b) (6) >
Colvis, Christine (NIH/NCATS) [E] < (b) (6) > Deming, Damon (FDA/CDER) < (b) (6) >
Diamond, Michael < (b) (6) > Duncan, Ken < (b) (6) >
Fernandes, Prabhavathi < (b) (6) > Fessel, Josh (NIH/NHLBI) [E] < (b) (6) >
Florence, Clint (NIH/NIAID) [E] < (b) (6) > Gadbois, Ellen (NIH/OD) [E] < (b) (6) >
Gatto, Greg < (b) (6) > Grobler, Jay < (b) (6) > Hewitt, Judith

(NIH/NIAID) [E] < (b) (6) Jonson, Samantha (NIH/NCATS) [E] < (b) (6) Lutz, Cat
< (b) (6) Nancy Haigwood < (b) (6) Nestle, Frank < (b) (6) Ottinger,
Elizabeth (NIH/NCATS) [E] < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Payne,
David < (b) (6) Pitt, Louise < (b) (6) Punturieri, Antonello (NIH/NHLBI) [E]
< (b) (6) Qashu, Felicia (NIH/OD) [E] < (b) (6) Rao, Srinivas
< (b) (6) Rappaport, Jay < (b) (6) Stegmeier, Frank < (b) (6)

Subject: Re: FW: Agenda and materials for the Protective Immune Responses Sub-Group meeting

Thanks Joe
Best regards
John

On Fri, 12 Jun 2020 at 3:50 PM, Menetski, Joseph (FNIH) [T] < (b) (6) wrote:

Dear Working group,

Our friends in the vaccines group have generated a list that will be interesting to think about.

From below, we should have Janet and Ashley talk to the group about including this list in our online resources?

“Janet Lathey (NIAID) and Ashley Smith (BARDA), who co-lead a USG working group on assay development. They kindly provided the attached draft list of assays under development through USG mechanisms. Janet will join our meeting next week to discuss the assays and engagement by vaccine developers with the labs running them.”

Joe

From: Santos, Michael (FNIH) [T] < (b) (6)
Sent: Wednesday, June 10, 2020 9:45 AM
To: Menetski, Joseph (FNIH) [T] < (b) (6) Alvarez, Rosa Maria < (b) (6)
Cc: Tolman, Brett < (b) (6)
Subject: FW: Agenda and materials for the Protective Immune Responses Sub-Group meeting

Hi Joe and Rosa,

I meant to follow up to you last night: FYI on the attached assay tracker from the USG assay WG co-chairs (Janet Lathey and Ashley Smith). If there's anything of interest here, Janet Lathey will be at next week's sub-group meeting on this topic.

Thanks,
Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Tuesday, June 9, 2020 11:00 PM

To: (b) (6) (b) (6) (b) (6) (b) (6)
Gruber, Marion (FDA/CBER) <(b) (6)> Marks, Peter (FDA/CBER) <(b) (6)>
(b) (6) (b) (6) Arvin, Ann <(b) (6)> Michael, Nelson L CIV USARMY
MEDCOM WRAIR (USA) (b) (6) Bett, Andrew J (b) (6) Gilbert PhD,
Peter B <(b) (6)> Kathleen Neuzil <(b) (6)> Modjarrad, Kayvon CIV USARMY
MEDCOM WRAIR (USA) <(b) (6)> Thornburg, Natalie (CDC/DDID/NCIRD/DVD)
<(b) (6)> Greg Glenn <(b) (6)> Cavaleri Marco <(b) (6)> Kelly, Beth
<(b) (6)>
Cc: Tolman, Brett <(b) (6)> (b) (6) (b) (6)
denise (b) (6) Jeneffer Haynes <(b) (6)> Menetski, Joseph (FNIH) [T]
<(b) (6)> Alvarez, Rosa Maria <(b) (6)> Wholley, David (FNIH) [T]
<(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Brian Rosen <(b) (6)>
Cheryl Keech <(b) (6)>

Subject: Agenda and materials for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting at 2:30pm ET (11:30am PT / 6:30pm CEST).

Last week we were fortunate to have Marco Cavaleri present and lead a discussion on EMA regulatory pathways. Development of a table of those pathways analogous to the table developed for FDA pathways is underway.

At this meeting we will return to the topics from two weeks ago: (1) reaching out to collect information on potential signals of human immunity and (2) inter-comparability of immunogenicity assays and centralized labs.

Since that meeting Ann and Mark Davis discussed the first topic, and reached out to Dan Rotrosen (Director of the Division of Allergy, Immunology, and Transplantation at NIAID). He is unfortunately unable to join this meeting, but we will discuss the categories of information we would like to collect and the potential process for doing so.

On the second topic, we reached out to Janet Lathey (NIAID) and Ashley Smith (BARDA), who co-lead a USG working group on assay development. They kindly provided the attached draft list of assays under development through USG mechanisms. Janet will join our meeting next week to discuss the assays and engagement by vaccine developers with the labs running them.

Please let us know if you have any questions or suggestions.

Best regards,

Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Wednesday, June 3, 2020 11:30 PM

Subject: Notes from yesterday's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting, and particular thanks to Marco for the excellent presentation and discussion.

Meeting notes are attached, with the meeting materials are embedded. The key action item is developing a table of EMA pathways analogous to the one that we previously developed with Marion's input and review for FDA pathways.

Please reach out with any additions or edits to the notes, questions, or suggestions.

Best regards,

Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Monday, June 1, 2020 1:04 PM

Subject: Agenda and materials for the Protective Immune Responses Sub-Group meeting tomorrow (Tuesday)

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting tomorrow (Tuesday) at 8am ET (5am PT / 2pm CEST). We are very sorry for the extremely early start PT.

The main agenda item is to discuss EMA and member state regulatory pathways to vaccine use and approval. Marco will lead the discussion. He previously shared a set of presentation slides (re-attached here). We are also re-attaching the table on FDA pathways that we circulated previously.

Please let us know if you have any questions or suggestions.

Best regards,

Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Thursday, May 28, 2020 12:57 PM
Subject: Notes and next steps from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting. Notes are attached.

There were two key areas for next steps that we identified in the meeting:

- Potential signals of human immunity:
 - Develop specifics of what we are looking for from immunology research
 - Ask the WG and other contacts for suggestions of researchers/organizations worth reaching out to
 - Reach out and collect information and contacts to engage with the WG (in presentations or other formats)
- Inter-comparability of immunogenicity assays / centralized labs
 - Reach out to NIAID to learn more about planned centralized lab capabilities and timing

Ann kindly followed up with an initial set of recommendations for the first area. We'll be following up to develop the list of information that we'd like to gather and to discuss how to prioritize whom we reach out to. We'll reach out to NIAID and report back on the second area.

We think these topics will form the basis for future discussions, but we are also trying to schedule a meeting for a time when we can have a discussion about the EMA regulatory pathways with Marco, to complement the conversations we have had on FDA pathways. We hope to have an invite for that out soon.

As always, please reach out with any additional input on the notes, questions, or suggestions for future directions for this group.

Best regards,

Brett and Mike

Michael Santos, PhD

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 11:42 PM
Subject: Agenda for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to today's (Wednesday) meeting, at 9am ET (6am PT / 3pm CEST).

Since our last meeting, Marco kindly shared the attached document on EMA and member state regulatory pathways for vaccine use and approval. Unfortunately Marco won't be able to join this meeting, but has offered to discuss the EMA pathways at a future meeting.

Our recent meetings have focused primarily on understanding regulatory pathways for vaccine use and approval, and the types of evidence that factor into regulatory decisions for different pathways, with two presentations on upcoming sources of evidence (NIAID NHP challenge studies using sera/IgG/mAbs and CDC immunological studies). A key goal of this group is to facilitate vaccine developers to generate evidence that can support evaluation of vaccine efficacy. For today's meeting, we plan to discuss the different categories of evidence and identify priorities for ACTIV to engage to be supportive.

We look forward to the discussion. If you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,

Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 12:19 AM
Subject: Notes from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached notes and materials from our meeting last week. Thanks again to Donna and Natalie for presenting, and as always to Marion for her contributions to the regulatory pathways during the meeting and subsequently.

We will be in touch again soon regarding this week's meeting. Feel free to reach out any time with questions or suggestions.

Best regards,

Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 19, 2020 8:56 AM
Subject: Agenda and Materials for today's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached two documents for today's Protective Immune Responses Sub-Group meeting (2pm ET / 11am PT / 8pm CEST):

- An updated table of pathways to vaccine use
- Notes from the last Sub-Group meeting (with my apologies for the delay)

For today's meeting, the agenda items are:

- Discussion of the updated pathways table and next steps
- An overview of the CDC's serology activities by Natalie

We're looking forward to the discussion today. As always, if you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,

Brett and Mike

Michael Santos, PhD

Associate Vice President, Science

Foundation for the National Institutes of Health

(b) (6) | fnih.org

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 10/10/2020 9:33:56 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: Roster of ACTIV Vaccines WG
Flag: Follow up

Hi Francis,

In case you were looking for the opposite of what I sent in my previous email, this is the list of WG members who are also on the Clinical Trials Sub-Group.

Thanks,
Mike

Name	Organization
Paula Annunziato	Merck
Larry Corey	Fred Hutch
Ann Arvin	Stanford
Beth Bell	UW
Marco Cavaleri	EMA
Emilio Emini	Gates
Gregory M. Glenn	Novavax
Marion Gruber	CBER/FDA
Peter Hotez	Baylor and Texas Children's
Kathrin Jansen	Pfizer
Doug Lowy	NCI/NIH
Peter Marks	CBER/FDA
John Mascola	VRC/NIH
Nelson Michael	WRAIR
Paul Offit	Penn/CHOP
Tal Zaks	Moderna

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Saturday, October 10, 2020 3:10 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Freire, Maria

Subject: RE: Roster of ACTIV Vaccines WG

Hi Francis,

Sure, no problem. The list below is only the non-WG members of the Sub-Group.

Thanks,

Mike

Name	Organization
Myron Cohen	UNC
Elizabeth Desrosiers	Merck
Macaya Douoguih	J&J
Peter Dull	Gates
Emily Erbeling	NIAID/NIH
Peter Gilbert	SCHARP/UW
Paul Gillard	GSK
Bill Gruber	Pfizer
Sanjay Gurunathan	Sanofi
Holli Hamilton	BARDA
Ian Hirsch	AZ
Laurent Humeau	Inovio
Cheryl Keech	Novavax
Kenneth Koury	Pfizer
Michael Kurilla	NCATS/NIH
Julie Ledgerwood	NIAID/NIH
Maarten Leyssen	J&J
Mary Marovich	NIAID/NIH
Hilary Marston	NIAID/NIH
Stacey Martin	CDC
Jacqueline Miller	Moderna
Kayvon Modjarrad	WRAIR
Kathleen Neuzil	Maryland
Ashley Parker	NIH
Merlin Robb	Henry Jackson Foundation
François Roman	GSK
Jerald Sadoff	J&J
Stephanie Schrag	CDC
Sheri Schully	NIH
Sandra Sitar	VRC/NIH
Saranya Sridhar	Sanofi
Jennifer Verani	CDC
Michael Watson	Moderna

Michael Santos, PhD

From: Collins, Francis (NIH/OD) [E] (b) (6)

Sent: Saturday, October 10, 2020 2:31 PM

To: Santos, Michael (FNIH) [T] (b) (6)

Cc: Lane, Cliff (NIH/NIAID) [E] <(b) (6)>; Wholley, David (FNIH) [T] <(b) (6)>; Freire, Maria (FNIH) [T] <(b) (6)>

Subject: Re: Roster of ACTIV Vaccines WG

Can you do me a favor and just pull out the names and institutions of the people who are not on the Vaccines WG?

Sent from my iPhone

On Oct 10, 2020, at 2:21 PM, Santos, Michael (FNIH) [T] <(b) (6)> wrote:

Hi Francis,

We don't maintain as nice of a version of the Sub-Group rosters, but here is the Clinical Trials Sub-Group list of names and organizations (some of which overlap with the main WG). We also commonly have additional guests depending on the topic, so if there's an organization or expertise that you're looking for that is not represented, we can invite them to a meeting ad hoc.

Thanks,
Mike

Name	Organization
Paula Annunziato (co-chair)	Merck
Larry Corey (co-chair)	Fred Hutch
Ann Arvin	Stanford
Beth Bell	UW
Marco Cavaleri	EMA
Myron Cohen	UNC
Elizabeth Desrosiers	Merck
Macaya Douoguih	J&J
Peter Dull	Gates
Emilio Emini	Gates
Emily Erbeling	NIAID/NIH
Gregory M. Glenn	Novavax
Peter Gilbert	SCHARP/UW
Paul Gillard	GSK
Bill Gruber	Pfizer
Marion Gruber	CBER/FDA
Sanjay Gurunathan	Sanofi
Holli Hamilton	BARDA
Ian Hirsch	AZ
Peter Hotez	Baylor and Texas Children's
Laurent Humeau	Inovio

Kathrin Jansen	Pfizer
Cheryl Keech	Novavax
Kenneth Koury	Pfizer
Michael Kurilla	NCATS/NIH
Julie Ledgerwood	NIAID/NIH
Maarten Leyssen	J&J
Doug Lowy	NCI/NIH
Peter Marks	CBER/FDA
Mary Marovich	NIAID/NIH
Hilary Marston	NIAID/NIH
Stacey Martin	CDC
John Mascola	VRC/NIH
Nelson Michael	WRAIR
Jacqueline Miller	Moderna
Kayvon Modjarrad	WRAIR
Kathleen Neuzil	Maryland
Paul Offit	Penn/CHOP
Ashley Parker	NIH
Merlin Robb	Henry Jackson Foundation
François Roman	GSK
Jerald Sadoff	J&J
Stephanie Schrag	CDC
Sheri Schully	NIH
Sandra Sitar	VRC/NIH
Saranya Sridhar	Sanofi
Jennifer Verani	CDC
Michael Watson	Moderna
Tal Zaks	Moderna

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Collins, Francis (NIH/OD) [E] <(b) (6)>

Sent: Saturday, October 10, 2020 12:47 PM

To: Santos, Michael (FNIH) [T] (b) (6) >

Cc: Lane, Cliff (NIH/NIAID) [E] (b) (6); Wholley, David (FNIH) [T] (b) (6)

Freire, Maria (FNIH) [T] (b) (6) >

Subject: RE: Roster of ACTIV Vaccines WG

Thanks, this is helpful. Have you got a roster of the Clinical Trials Sub-Group?

From: Santos, Michael (FNIH) [T] (b) (6) >

Sent: Saturday, October 10, 2020 11:47 AM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Cc: Lane, Cliff (NIH/NIAID) [E] (b) (6); Wholley, David (FNIH) [T] (b) (6)

Freire, Maria (FNIH) [T] (b) (6)

Subject: RE: Roster of ACTIV Vaccines WG

COLL0000013800-2517490

Hi Francis,

Sure, I'd be happy to convene a meeting of the WG.

The WG membership is attached. We also have a wider group of people that have been part of the sub-groups, so depending on the topic and the ask we could invite them as well (e.g., for a clinical trials question we could convene the WG plus the Clinical Trials Sub-Group).

For next steps, if we can know a little more about the topic and the desired timing, I'm happy to connect with Kathrin and Doug and schedule a meeting with the appropriate set of people.

Best regards,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Saturday, October 10, 2020 11:33 AM
To: Santos, Michael (FNIH) [T] (b) (6)
Cc: Lane, Cliff (NIH/NIAID) [E] (b) (6); Wholley, David (FNIH) [T] (b) (6);
Freire, Maria (FNIH) [T] (b) (6) >
Subject: Roster of ACTIV Vaccines WG

Hi Mike,

We might need to reconvene the ACTIV Vaccines WG for some advice about management of next steps for the trials. Can you send me the roster?

Francis

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/6/2021 6:35:17 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Speaking to ACTIV-2 today

Hi Francis,

My apologies for the late arrival in your inbox.

Please find below some suggested thoughts for your presentation in 30 minutes. Feel free to any that you feel are appropriate. I think the main point that the team was hoping for is just a strong show of NIH support from the top for all the efforts the sites have been putting in.

Please feel free to revise if needed:

- Appreciate all the dedication, hard work, and long hours contributed to ACTIV-2
- Understand that there have been many challenges to overcome:
 - Challenging routes of drug administration – IV infusions for mAbs
 - Rapid pace of the master protocol for site stand up and regulatory approvals
 - Fast addition of new agents causing continuous updates at the sites
- THANK YOU for your perseverance through all of these
- Congratulations on creating a vast and diverse network to reach patients where they are:
 - Over 150 sites open domestically and 100+ international sites ready to come onboard
 - Successful branding and promotional campaign
 - Continued dedication to reaching underserved communities: Successful deployment of the “Barber Shop” program and others
- Agents being tested are making a difference:
 - Over 1200 patients treated with Lilly’s bamlanivimab EUA authorized agent
 - Brie Bio advancing to Phase 3 testing
 - Brie Bio and AZ mAb cocktails and SAB polyclonal Abs seem to retain potency against the emerging variants of concern
 - Oral (camostat) and inhaled (IFN-beta) antivirals could provide much needed treatments that are not susceptible to the emerging variants

(b) (4)

- Strong desire and collaborative spirit to share what you have learned with other trials to help advance the field

Thanks,
Stacey

Stacey J. Adam, PhD
Associate Vice President
Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

From: Collins, Francis (NIH/OD) [E] <(b) (6)>

Sent: Tuesday, April 6, 2021 8:17 AM

To: Adam, Stacey (FNIH) [T] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)>

Subject: Speaking to ACTIV-2 today

Hi Stacey and David,

My calendar says I am speaking to the ACTIV-2 PIs today at 3 pm. I think this was supposed to be a “rally the troops” moment, thanking them for their hard work and encouraging continuing efforts. Can you suggest some specific points I should make with these folks?

Thanks, Francis

[(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd5cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Colli]; Amanda Peppercorn [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Gonzalez, Nina [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Tountas, Karen (FNIH) [T]

CC:

[/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Tolman, Brett
 [(b) (6) Alvarez, Rosa [(b) (6) Stratton, Benjamin [(b) (6)
 Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Chen, Helen Q.
 [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Elsaid, Olivia
 [(b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acb5fd03b3cf32930-walkerp1]; Kurilla, Michael
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Merritt, Gabriella Marie
 [(b) (6) Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Gonzalez, Nina
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
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 Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]; Freire, Maria (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Jansen,
 Kathrin [(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John
 (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6)
 Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla
 [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Dana Carluccio
 [(b) (6) Rose Li Central Account [(b) (6) Lucas Smalldon
 [(b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; jennifer.j. (b) (6) Mollica, Linda /US
 [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Bethany Stokes (b) (6)]

Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20201001_vF.pdf

Location: <https://fnih.zoom.us/> (b) (6)

Start: 10/1/2020 5:00:00 PM

End: 10/1/2020 6:00:00 PM

Show Time As: Tentative

Recurrence: (none)

every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Levy, Elliot; Jacqueline Kirchner; Garner, Carl; Bozette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; (b) (6); Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL;

(b) (6) Sizemore, Christine (NIH/FIC) [E]

Optional Attendees: Merritt, Gabriella Marie; Margaret Anderson; Gonzalez, Nina; Kurilla, Michael (NIH/NCATS) [E];

(b) (6) Stock, Thomas (HHS/IOS); Freire, Maria (FNIH) [T]; Desrosiers, Betsy; Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes

Dear ACTIV TX-Clinical WG,

Please find attached the slides for today's presentation.

Thanks,
Stacey

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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 4/16/2020 10:09:31 AM
To: Bascles, Lionel [(b) (6)] Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [lcorey@fredhutch.org]; Desrosiers, Betsy [(b) (6)] Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King.]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6)] Srinivasan, Badhri [(b) (6)] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [(b) (6)] Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6)] Jansen, Kathrin [(b) (6)] Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)] Criffield, Robin [(b) (6)] Hamilton, Nancy [(b) (6)] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [(b) (6)] Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6)] Carluccio, Dana [(b) (6)] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6)] James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [(b) (6)] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Wachtel, Jonathan [(b) (6)]
Subject: Clinical Trial Capacity WG - meeting #1 summary

Dear Clinical Trial Capacity Working Group colleagues,

Attached is a summary of meeting #1 of the Clinical Trial Capacity Working Group. It was a very good start to this effort; thank you to everyone for participating in this important initial discussion.

Looking forward to forming the subgroups and initiating detailed activities.

Karen

Karen H. Tountas, PhD

Scientific Program Manager

Foundation for the National Institutes of Health

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Sent: 4/17/2020 7:47:52 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Rose Li Central Account [(b) (6) Lucas Smalldon [(b) (6) Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US [(b) (6)

Subject: ACTIV Therapeutics-Clinical Master Protocol Subgroup - Meeting #

Location: <https://fnih.zoom.us/> (b) (6)

Start: 4/20/2020 6:00:00 PM

End: 4/20/2020 7:00:00 PM

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Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylvia (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER)

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Rose Li Central Account; Lucas Smalldon; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wung, Peter /US

Dear TX-Clinical Master Protocol Subgroup,

This will be our 4th meeting. We will update with materials closer to the meeting.

Thanks,

Stacey

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 6/8/2020 2:48:02 PM
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(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6)]; (b) (6)
Arvin, Ann [(b) (6) Beth Bell ((b) (6) [(b) (6)
(b) (6) Cavaleri Marco [(b) (6) (b) (6)
(b) (6) (b) (6) Greg Glenn [(b) (6)
(b) (6) Haynes, Barton [(b) (6) (b) (6) (b) (6)
Marks, Peter (FDA/CBER) [(b) (6) Mascola, John (NIH/VRC) [E] [(b) (6)
Messonnier, Nancy (CDC/DDID/NCIRD/OD) [(b) (6) Nelson Michael [(b) (6)
Offit, Paul [(b) (6) (b) (6) Seals, Jonathan (OS/ASPR/BARDA)
[(b) (6) (b) (6) (b) (6) Tal Zaks
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(b) (6) (b) (6) (b) (6)
CC: Tolman, Brett [(b) (6) (b) (6) Hopps, Markay [(b) (6)
Kozlowski, Mary (NIH/NCI) [C] [(b) (6) Johnson, Maureen (NIH/NCI) [E]
[(b) (6) (b) (6) Jeneffer Haynes [(b) (6)
(b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]
[(b) (6) (b) (6) Isabel Ramsey [(b) (6) Parker,
Ashley (NIH/OD) [E] [(b) (6) Marston, Hilary (NIH/NIAID) [E] [hi (b) (6)]; Qashu,
Felicia (NIH/OD) [E] (b) (6) Culp, Michelle (NIH/OD) [E] [(b) (6) Gadbois, Ellen
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadbois]; Wholley, David (FNIH) [T]
(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Menetski, Joseph (FNIH) [T]
[(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6)
James, Stephanie (FNIH) [T] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6)
Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Kurilla, Michael
(NIH/NCATS) [E] [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Young, John
[(b) (6) Paul Gillard [(b) (6) Hamilton, Holli (OS/ASPR/BARDA)
[(b) (6) Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA)
[(b) (6) Kathleen Neuzil [(b) (6) Schrag, Stephanie
(CDC/DDID/NCIRD/DBD) [(b) (6) Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [(b) (6)
Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [(b) (6) Gonzalez, Nina [(b) (6) 'Wachtel,
Jonathan' [(b) (6) Stratton, Benjamin [(b) (6) (b) (6)
(b) (6) Bethany Stokes [(b) (6) m]; Kathleen Callahan
[(b) (6) Kayvon Modjarrad [(b) (6) Arvin, Ann [(b) (6)
Anderson, Margaret [(b) (6)

Subject: ACTIV Vaccines Working Group meeting

Location: Webex: <https://nih.webex.com/nih> (b) (6)

Start: 6/24/2020 3:00:00 PM

End: 6/24/2020 4:00:00 PM

Show Time As: Tentative

Required Attendees: (b) (6) (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6)
Arvin, Ann; Beth Bell ((b) (6) (b) (6) Cavaleri Marco; (b) (6)
(b) (6) (b) (6) Greg Glenn; (b) (6) Haynes,
Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];
Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6) Seals, Jonathan
(OS/ASPR/BARDA); (b) (6) (b) (6) Tal Zaks; (b) (6)
svein. (b) (6) (b) (6) (b) (6) (b) (6)
(b) (6)

Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen (NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)
(b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker, Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret; (b) (6) (b) (6); Bethany Stokes; Kathleen Callahan; Kayvon Modjarrad; Arvin, Ann

-- Do not delete or change any of the following text. --

Join Webex meeting

Meeting number (access code): (b) (6) Meeting password: (b) (6)

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If you are a host, click here to view host information. IMPORTANT NOTICE: Please note that this Webex service allows audio and other information sent during the session to be recorded, which may be discoverable in a legal matter. By joining this session, you automatically consent to such recordings. If you do not consent to being recorded, discuss your concerns with the host or do not join the session.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/17/2020 6:15:35 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: ChAdOx1
Flag: Follow up

Thanks – sorry , sent my other note before I saw this one.

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Saturday, May 16, 2020 8:00 PM
To: Marks, Peter (FDA/CBER) <(b) (6)> ; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>
Mascola, John (NIH/VRC) [E] <(b) (6)> ; Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Cc: Wholley, David (FNIH) [T] <(b) (6)> ; Tabak, Lawrence (NIH/OD) [E] <(b) (6)> ; Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: RE: ChAdOx1

Just a brief word of concern – let's be sure we don't come down too strong on Pfizer's role in the recent vaccine WG discussions. One could argue they expressed a perspective that needed to be heard, though not embraced. We don't want to put Pfizer leadership in a position that might lead to their decision to pull out of ACTIV. Better to draw them in more closely.

From: Marks, Peter <(b) (6)>
Sent: Saturday, May 16, 2020 3:13 PM
To: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> ; Mascola, John (NIH/VRC) [E] <(b) (6)>
Collins, Francis (NIH/OD) [E] <(b) (6)> ; Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Cc: Wholley, David (FNIH) [T] <(b) (6)> ; Tabak, Lawrence (NIH/OD) [E] <(b) (6)> ; Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: RE: ChAdOx1

Dear Tony,

Will certainly include you next week on this call.

Best Regards,
Peter

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>
Sent: Thursday, May 14, 2020 9:12 AM
To: Marks, Peter <(b) (6)> >; Mascola, John R (NIH) <(b) (6)> >; Collins, Francis S (NIH) <(b) (6)> ; Lane, Henry C (NIH) <(b) (6)>
Cc: Wholley, David N (NIH) <(b) (6)> ; Tabak, Lawrence A (NIH) <(b) (6)> ; Parker, Ashley S (NIH) <(b) (6)>
Subject: RE: ChAdOx1

I would also like to be on that call with the Pfizer CEO if we could possible arrange it.

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
Building 31, Room 7A-03
31 Center Drive, MSC 2520
National Institutes of Health
Bethesda, MD 20892-2520
Phone: (b) (6)
FAX: (301) 496-4409
E-mail: (b) (6)

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From: Marks, Peter (b) (6)
Sent: Thursday, May 14, 2020 9:05 AM
To: Mascola, John (NIH/VRC) [E] (b) (6) >; Collins, Francis (NIH/OD) [E] (b) (6) >; Lane, Cliff (NIH/NIAID) [E] (b) (6)
Cc: Fauci, Anthony (NIH/NIAID) [E] (b) (6); Wholley, David (FNIH) [T] < (b) (6) >; Tabak, Lawrence (NIH/OD) [E] (b) (6); Parker, Ashley (NIH/OD) [E] (b) (6) >
Subject: RE: ChAdOx1

Dear John,

Thanks for bringing the Pfizer issue up. I think that a call with their head of development and possibly also their CEO may be needed, and I wonder if Francis would like to join?

Best Regards,
Peter

From: Mascola, John (NIH/VRC) [E] (b) (6)
Sent: Thursday, May 14, 2020 9:03 AM
To: Marks, Peter (b) (6) >; Collins, Francis S (NIH) < (b) (6) >; Lane, Henry C (NIH) (b) (6)
Cc: Fauci, Anthony S (NIH) (b) (6); Wholley, David N (NIH) < (b) (6) >; Tabak, Lawrence A (NIH) < (b) (6) >; Parker, Ashley S (NIH) < (b) (6) >
Subject: RE: ChAdOx1

Francis - we did make good progress on ACTIV Vaccine WG. Yesterday on the vaccine clinical trials subgroup, we presented the harmonized protocol approach and high level details of phase 3 design. There was good input on both and general agreement, with some useful recommendations on efficient ways to conduct phase 3.

One issues is that the Pfizer representative on the subgroup, both Kathrin Jansen (who is co-chair of Vaccines WG), and Bill Gruber (Pfizer Senior VP for R&D) – took turns articulating their view that large Pharma companies like theirs prefer not to work with USG and it would just slow them down. When we asked for suggestions for DSMB, Kathrin said she did not agree that we should ask for nominations – because this issue required more discussion – mainly because Pfizer has no interest in this. Doug Lowy was on the call, so may be useful to get his perspective.

John

From: Marks, Peter (b) (6)
Sent: Thursday, May 14, 2020 6:23 AM
To: Collins, Francis (NIH/OD) [E] (b) (6) >; Mascola, John (NIH/VRC) [E] < (b) (6) >; Lane, Cliff (NIH/NIAID) [E] < (b) (6) >
Cc: Fauci, Anthony (NIH/NIAID) [E] < (b) (6) >; Wholley, David (FNIH) [T] (b) (6) >; Tabak, Lawrence (NIH/OD) [E] < (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6)
Subject: RE: ChAdOx1

Dear Francis,

We had made good progress with the Oxford AZ team on the clinical end before the contracting period began. From my last conversation with the AZ clinical team they were on board with the USG concept of a large phase 3 trial, potentially as part of a master protocol if the timing was right. Their major issue was getting moving rapidly.

Among other things, Tony, John and I discussed the concept that (b) (5)

(b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5). Happy to discuss further.

Best Regards,
Peter

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Thursday, May 14, 2020 5:38 AM
To: Mascola, John R (NIH) < (b) (6) >; Lane, Henry C (NIH) < (b) (6) >; Marks, Peter < (b) (6) >
Cc: Fauci, Anthony S (NIH) (b) (6) >; Wholley, David N (NIH) (b) (6) >; Tabak, Lawrence A (NIH) < (b) (6) >; Parker, Ashley S (NIH) < (b) (6) >
Subject: ChAdOx1

Gentlemen:

I need to know the update on where we are with Oxford, A-Z, and ChAdOx1. I see there's a BARDA WebEx at 5 pm, and I have a rescheduled phone call this morning with John Bell. I'd like to be as useful as possible in making a plan that

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includes this vaccine program as part of the harmonized master protocol. Advice about how to use the call with John Bell most effectively would be most welcome!

And did the Vaccines WG make good progress yesterday on the details of the harmonized master protocol? Did they agree in principle to a single DSMB?

Thanks, Francis

From: Wung, Peter /US (b) (6)
Sent: 5/14/2020 6:24:49 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Dear Francis,

Thank you for including me in this important endeavor with the NIH.

I am comfortable with my name listed on the website.

Regards,
Peter

Peter K. Wung, MD, MHS, FACR

AVP, Global OMD Lead I&I
Clinical Sciences & Operations | Research & Development

55 CORPORATE DRIVE - BRIDGEWATER - New Jersey 08807

Cell: + (b) (6)
(b) (6)



From: Collins, Francis (NIH/OD) [E] < (b) (6) >
Sent: Thursday, May 14, 2020 10:00 AM
To: Collins, Francis (NIH/OD) [E] < (b) (6) >
Cc: Myles, Renate (NIH/OD) [E] < (b) (6) > Meltzer, Abbey (FNIH) [T] < (b) (6) > Wholley, David (FNIH) [T] < (b) (6) >
Subject: [EXTERNAL] Time sensitive: Making your ACTIV Participation Public

EXTERNAL : Real sender is (b) (6)

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on

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ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 4/12/2020 4:49:41 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; david.j. (b) (6)
(b) (6); (b) (6); (b) (6); (b) (6)
(b) (6); (b) (6); (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] (b) (6) Colvis, Christine (NIH/NCATS) [E] (b) (6) Hewitt, Judith (NIH/NIAID) [E] (b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6); (b) (6); (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras];
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Rao, Srinivas /US
(b) (6)
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Rodriguez, Robin D [(b) (6) Stratton, Benjamin [(b) (6) Gonzalez, Nina [(b) (6)
Subject: COVID Preclinical Working group Meeting #2
Attachments: PRECLINICAL Working Group FNIH_Meeting_2_0417_vF4.pdf; 20200416_PRECLINICAL Working Group_Animal Models_Actions and observations_d3.docx; Inventory Template columns for WG review_4 16 2020.xlsx; In vitro Subteam notes and actions 4 16 d4.docx

Location: <https://zoom.us/> (b) (6)

Start: 4/17/2020 3:00:00 PM

End: 4/17/2020 4:00:00 PM

Show Time As: Busy

Required Attendees: Menetski, Joseph (FNIH) [T]; (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Parker, Ashley (NIH/OD) [E]; (b) (6) Adams, Peter
(OS/ASPR/BARDA); Jonson, Samantha (NIH/NCATS) [E]; Rao, Srinivas /US
Optional Attendees: Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Rodriguez, Robin D; Stratton, Benjamin; Gonzalez, Nina

Saving time on the calendar.

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

<https://zoom.us/> (b) (6)

Meeting ID: (b) (6)

Password: (b) (6)

One tap mobile

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US (New York)

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JS (San Jose)
JS
JS
JS (Houston)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: [https://zoom.us/j/](https://zoom.us/j/(b)(6)) (b) (6)

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/15/2020 11:27:01 PM
To: Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)]; Rose Li Central Account [(b) (6)]; Lucas Smalldon [(b) (6)]; Salathin, Carla [(b) (6)]; [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Formal Summary from ACTIV TX-Clinical WG Agent Prioritization Subgroup - 1st Meeting
Attachments: ACTIVPrioritizationCriteria-v2.xlsx; 2020-04-14_TX-Clinical_WG_Agent_Prioritization_Subgroup_Summary.pdf

Dear ACTIV TX-Clinical WG Agent Prioritization Subgroup Members,

Please find attached the full meeting summary from yesterday's call. Let us know if you have any additions that you think we may need to make.

In addition, this is a reminder to please provide you feedback on the attached spreadsheet that the co-chairs have compiled to reflect the data needed for the draft criteria. Please let us know your thoughts on this, as well.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

From: Adam, Stacey (FNIH) [T]
Sent: Wednesday, April 15, 2020 8:42 AM
To: Eric Hughes < (b) (6) >; Read, Sarah (NIH/NIAID) [E] < (b) (6) >; Ruxandra Draghia-Akli < (b) (6) >; John Mellors < (b) (6) >; Naimish Patel < (b) (6) >; Colvis, Christine (NIH/NCATS) [E] < (b) (6) >; Young, John < (b) (6) >; Stein, Peter (FDA/CDER) < (b) (6) >; Poole, Mike < (b) (6) >; Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b) (6) >; Vincent, Michael < (b) (6) >;
Cc: Elizabeth Kim < (b) (6) >; Menetski, Joseph (FNIH) [T] < (b) (6) >; Alvarez, Rosa Maria < (b) (6) >; Rose Li Central Account < (b) (6) >; Lucas Smalldon

< (b) (6) Salathin, Carla < (b) (6) (b) (6)
(b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Wholley, David (FNIH) [T] < (b) (6)
Melencio, Cheryl (FNIH) [T] < (b) (6)

Subject: Follow-up from ACTIV TX-Clinical WG Agent Prioritization Subgroup - 1st Meeting

Dear ACTIV TX-Clinical WG Agent Prioritization Subgroup Members,

Thank you all so much for getting together so quickly for second meeting yesterday. We appreciate all your contributions and I think we made good progress.

Please see attached the high level summary points that we captured, including DRAFT criteria and DRAFT data needed for the criteria. Please let us know your thoughts. Based on this information our co-chairs have created the attached excel spreadsheet as a model for needed data capture. Please let us know your thoughts on this, as well. We will be working to try and turn this into a decision flow diagram for easy review, so your quick response on suggested modifications would be appreciated.

Finally, you will receive this again at the larger WG a little later, but since we were discussing publication and early data/results needs. Please let us know if this publication/literature database exclusively for COVID-19 that NIH has created would be helpful for this purpose.

NIH is supporting a publication database on everything that has been published about COVID-19, generated by NIH Office of Portfolio Analysis (OPA).

- OPA has developed a comprehensive, human-curated portfolio of COVID 19 publications and preprints (<https://icite.od.nih.gov/covid19/search/>)
- This includes peer-reviewed articles from PubMed and preprints from medRxiv, bioRxiv, ChemRxiv, and arXiv. It is updated daily and enables users to leverage the iSearch platform to interrogate manually curated preprints, peer-reviewed publications, and all associated supplemental data from each

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
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To: Stein, Peter (FDA/CDER) [(b) (6)]; Cohen, Myron [(b) (6)]; Victoria Davey [(b) (6)]; Dickens, Jim (NIH/NCATS) [(b) (6)]; Doroshow, James (NIH/NCI) [(b) (6)]; Goff, David (NIH/NHLBI) [(b) (6)]; Kurilla, Michael (NIH/NCATS) [(b) (6)]; Mensah, George (NIH/NHLBI) [(b) (6)]; Nayak, Seema (NIH/NIAID) [(b) (6)]; Payton, Manizhe (NIH/NIAID) [(b) (6)]; Sizemore, Christine (NIH/FIC) [(b) (6)]; Weinmann, Gail (NIH/NHLBI) [(b) (6)]; Tountas, Karen (FNIH) [(b) (6)];
 [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Stein, Peter (FDA/CDER) [(b) (6)];
 [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [(b) (6)]; Bascles, Lionel [(b) (6)]; Cohen, Myron [(b) (6)];
 [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6)]; Victoria Davey [(b) (6)];
 [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [(b) (6)]; Dickens, Jim (NIH/NCATS) [(b) (6)];
 [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [(b) (6)];
 [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Garner, Carlos [(b) (6)];
 [(b) (6)] Goff, David (NIH/NHLBI) [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [(b) (6)];
 [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [(b) (6)];
 [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [(b) (6)];
 [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [(b) (6)];
 [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6)];
 [(b) (6)] Sizemore, Christine (NIH/FIC) [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [(b) (6)];
 [(b) (6)] Weinmann, Gail (NIH/NHLBI) [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]; Kublin MD, MPH, James [(b) (6)];
 [(b) (6)] Ferguson, Sue [(b) (6)];
CC: Colvis, Christine (NIH/NCATS) [(b) (6)]; Lowy, Douglas (NCI) [(b) (6)]; Read, Sarah (NIH/NIAID) [(b) (6)];
 [(b) (6)] .gov]; Adam, Stacey (FNIH) [(b) (6)]; Melencio, Cheryl (FNIH) [(b) (6)];
 [(b) (6)] Gonzalez, Nina [(b) (6)]; James, Stephanie (FNIH) [(b) (6)]; Menetski, Joseph (FNIH) [(b) (6)];
 [(b) (6)] Qashu, Felicia (NIH/OD) [(b) (6)]; Santos, Michael (FNIH) [(b) (6)];
 [(b) (6)] Wholley, David (FNIH) [(b) (6)]; Hill, Zoe (NIH/NHLBI) [(b) (6)];
 [(b) (6)] Pico, Dianna (NIH/NHLBI) [(b) (6)]; Katz, Rebecca (NIH/NCATS) [(b) (6)];
 [(b) (6)] Culp, Michelle (NIH/OD) [(b) (6)]; Gadbois, Ellen (NIH/OD) [(b) (6)];
 [(b) (6)]; Kenny, Dermot [(b) (6)]; Takas, Therese [(b) (6)];
 [(b) (6)] Wachtel, Jonathan [(b) (6)]; Colvis, Christine (NIH/NCATS) [(b) (6)];
 [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6)];
 [(b) (6)] Jansen, Kathrin [(b) (6)]; Lowy, Douglas (NCI) [(b) (6)];
 [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [(b) (6)];
 [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)];
 [(b) (6)] Adam, Stacey (FNIH) [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6)];
 [(b) (6)] Parker, Ashley (NIH/OD) [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [(b) (6)];
 [(b) (6)] Melencio, Cheryl (FNIH) [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [(b) (6)];
 [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];

Heaton, Penny [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose (b) (6) ; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuvevsson, Nancy [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [(b) (6) Hamilton, Nancy [(b) (6) Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Minnich, Beth (b) (6) Mueller-Reichenstein, Petra [(b) (6) Pico, Dianna (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora [(b) (6) Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; (b) (6)

Attachments: Clinical Trial Capacity Working Group Meeting Agenda_06092020.pdf

Location: <https://fnih.zoom.us/j> (b) (6)

Start: 6/9/2020 1:00:00 PM

End: 6/9/2020 2:00:00 PM

Recurrence: (none)

Required Attendees: Stein, Peter (FDA/CDER); Vincent, Mike; Bascles, Lionel; Cohen, Myron; Corey, Larry; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Garner, Carlos; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Mensah, George; Nayak, Seema (NIH/NIAID) [E]; Payton, Manzone; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri; Weinmann, Gail; Kublin MD, MPH, James; Ferguson, Sue

Optional Attendees: Kenny, Dermot; Takas, Therese; (b) (6) Wachtel, Jonathan; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E] (b) (6) Carluccio, Dana; Cheryl (FNIH) Melencio [T] (b) (6) Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Qashu, Felicia; Santos, Michael (FNIH); Tuvevsson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Hill, Zoe (NIH/NHLBI) [C]; Minnich, Beth; Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] (b) (6) Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; (b) (6)

Dear Colleagues – Attached is the agenda for the call. Looking forward to an interesting call and your constructive dashboard feedback. Best regards, Karen

CT Capacity working group members, Many thanks for all the hard work that you have put into meeting our ACTIV mandate – looking forward to operationalizing the outcomes of your efforts. Let's continue to meet regularly through the month of June (once a week) to continue to build out the inventories of CROs/SMOs/Networks/Sites and innovation/efficiencies, where needed, and, to integrate with other ACTIV working groups in support of protocol implementation (treatment and prevention). Best regards, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

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To: Read, Sarah (NIH/NIAID) [E] [(b) (6)] Proschan, Michael (NIH/NIAID) [E] [(b) (6)] Mellors, John W [(b) (6)] Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6)] Eisner, Mark [(b) (6)] Gottesdiener, Keith [(b) (6)] Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6)] LaVange, Lisa [(b) (6)] Levy, Elliot [(b) (6)] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6)] Peppercorn, Amanda [(b) (6)] Poole, Mike [(b) (6)] Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collis]; Amanda Peppercorn [(b) (6)] Garner, Carl [(b) (6)] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96c8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6)] Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

CC: Sorosa, Alex David [(b) (6) Elsaid, Olivia [(b) (6) Chen, Helen Q. [(b) (6) Stratton, Benjamin [(b) (6) Gonzalez, Nina [(b) (6) Alvarez, Rosa [(b) (6) Tolman, Brett [(b) (6) Derek Smith [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Lucas Smalldon [(b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; [(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Bethany Stokes

[(b) (6) Sorosa, Alex David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]

Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20201022.pdf

Start: 10/22/2020 5:00:00 PM
End: 10/22/2020 6:00:00 PM

Recurrence: (none)

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]

Optional Attendees: Derek Smith; Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Margaret Anderson; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes; Sorosa, Alex David

Dear ACTIV TX-Clinical WG,

Please find attached the slides for today.

Thanks,
Stacey

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From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 7/29/2020 11:08:11 AM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Summary of yesterday's CP RCT meeting
Attachments: Convalescent Plasma Randomized Clinical Trials Meeting Summary 072820 clean.docx

With much thanks to Ashley, here's a summary of what happened at the CP RCT meeting yesterday.

Francis

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 8/18/2020 2:23:37 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Pao, William [(b) (6) Plump, Andrew [(b) (6) Stoffels, Paul [(b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [(b) (6) Anderson, Margaret [(b) (6) Chen, Helen [(b) (6) Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Tolman, Brett [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Castillejos, Carlos [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; FNIH Central Account [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Parker, Ashley (NIH/OD) [E]

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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Perala, Mie
[(b) (6) Protasiewicz, Ann [(b) (6) Riccobene, Kim
[(b) (6) Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togashi, Mieko (NIH/NCI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Underwood, Nancy
[(b) (6) Zottoli, Jessica [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Hughes, Karen (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Lagos, Enrique
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Sepulveda, Dorina (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD)
[C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Tajalli, Ada (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4fd4747b0d954e27855c241b28562547-tajallian]

Subject: ACTIV EC & Working Group Co-Chair Meeting

Location: <https://fnih.zoom.us/> (b) (6)

Start: 9/9/2020 1:00:00 PM

End: 9/9/2020 2:00:00 PM

Show Time As: Tentative

Required Attendees: Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Hawk, Harrison; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]

Optional Attendees: Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; Culp, Michelle (NIH/OD) [E]; FNIH Central Account; Gadbois, Ellen (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas,

Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Tajalli, Ada (NIH/OD) [E]

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Find your local number: <https://fnih.zoom.us> (b) (6)

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/11/2020 7:01:39 PM
To: Jim Neaton [(b) (6)] Jens Lundgren [(b) (6)] Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Eric Hughes [(b) (6)] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Srinivasan, Badhri [(b) (6)] Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Tierney, John (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61553b35beb7479789a06defda628627-jtierney]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [(b) (6)] William Erhardt [(b) (6)] Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; (b) (6) Gelijns, Annetine [(b) (6)] Mark Polizzotto [(b) (6)] Ginny Kan [(b) (6)] Baker, Jason [(b) (6)] Roger Paredes [(b) (6)] Thompson, Taylor, M.D. [(b) (6)] Babiker, Ab [(b) (6)]
CC: Chen, Helen Q. [(b) (6)] Wachtel, Jonathan [(b) (6)] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Desrosiers, Elizabeth A. [(b) (6)] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Kenny, Dermot [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Pett, Sarah [(b) (6)] Grace, Beth (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75f1e9e678842258cf6472505f68cd8-bgrace]; Barrett, Kevin (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0490b8cf48984327b737d027f4fddd81-barrett2]; Denning, Eileen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc3c18df3b7945bda704a01abd12b3b4-eileen.ccb]r]
Subject: ACTIV-3 Operations Team Meeting
Location: <https://fnih.zoom.us/> (b) (6)
Start: 6/16/2020 3:00:00 PM
End: 6/16/2020 4:00:00 PM
Show Time As: Tentative

Required Attendees: Jim Neaton; Jens Lundgren; Read, Sarah (NIH/NIAID) [E]; Eric Hughes; Higgs, Elizabeth (NIH/NIAID) [E]; Srinivasan, Badhri; Goff, David (NIH/NHLBI) [E]; Nayak, Seema (NIH/NIAID) [E]; Victoria Davey; Kozak, Marina (OS/ASPR/BARDA); McNay, Laura (NIH/NIAID) [E]; Tierney, John (NIH/NIAID) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Patterson, Amy (NIH/NHLBI) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; William Erhardt; Reineck, Lora (NIH/NHLBI) [E]; (b) (6) Gelijns, Annetine; Mark Polizzotto; Ginny Kan; Baker, Jason; Roger Paredes; Thompson, Taylor, M.D.; Babiker, Ab

Optional Attendees: Chen, Helen Q.; Wachtel, Jonathan; Tountas, Karen (FNIH) [T]; Desrosiers, Elizabeth A.; Kurilla, Michael (NIH/NCATS) [E]; Kenny, Dermot; Parker, Ashley (NIH/OD) [E]; Pett, Sarah; Grace, Beth (NIH/NIAID) [C]; Barrett, Kevin (NIH/NIAID) [E]; Denning, Eileen

Stacey Adam is inviting you to a scheduled Zoom meeting.

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(b) (6) US (Houston)
(b) (6) US (San Jose)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

Sent: 5/15/2020 1:44:15 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: FW: Time sensitive: Making your ACTIV Participation Public
Attachments: Leadership _ National Institutes of Health (NIH).pdf

Hi Lauren,

One things that would be helpful – can we cross check the updated list Renate shared with the attached spreadsheet of emails

From: Myles, Renate (NIH/OD) [E] <(b) (6)>
Sent: Friday, May 15, 2020 9:21 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Allen-Gifford, Patrice (NIH/OD) [E] <(b) (6)> Wooldridge, Shannon (NIH/OD) [E] <(b) (6)> Pollock, Rachel (NIH/OD) [E] <(b) (6)>
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Ashley:

Attached is the full list of members currently listed on the website in staging. I received the list from FNIH communications. Please let me know of any changes.

Thanks,
Renate

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Friday, May 15, 2020 9:11 AM
To: Myles, Renate (NIH/OD) [E] <(b) (6)>; Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Allen-Gifford, Patrice (NIH/OD) [E] <(b) (6)>; Wooldridge, Shannon (NIH/OD) [E] <(b) (6)> Pollock, Rachel (NIH/OD) [E] <(b) (6)>
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Renate,

I've added the emails below but we have a major version control issues. I've been working with Cheryl to receive updates and did not have Sylvia Collins, Beth Bell and Jonathan Seals and apparently they are listed on a separate list the FNIH communications team is tracking.

We can send follow up emails to everyone except for those three – they will need to be contacted.

Moving forward, it may be best for you to receive updates from the communications team – FNIH is managing multiple spreadsheets one for the emails Cheryl is managing to schedule meetings and a separate list for the communications office.

Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

(b) (6)

Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration

(b) (6)

Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader
RTI International

(b) (6)

Jay Grobler, Ph.D.

Director, Infectious Disease Biology
Merck & Co., Inc.

(b) (6)

Cat Lutz, Ph.D.

Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center
The Jackson Laboratory

(b) (6)

David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit
GlaxoSmithKline

(b) (6)

Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases

(b) (6)

Srinivas Rao, DVM, Ph.D.

Global Head, Translational In Vivo Models Global Research Platform
Sanofi

(b) (6)

Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology
Director and Chief Academic Officer
Tulane University National Primate Research Center

(b) (6)

Frank Stegmeier, Ph.D.

Chief Scientific Officer
KSQ Therapeutics

(b) (6)

Sylva Collins, Ph.D.

Director, Office of Biostatistics
U.S. Food and Drug Administration

(b) (6)

Judith Currier, M.D.

Professor of Medicine

University of California Los Angeles
Division of Infectious Diseases
Chair, AIDS Clinical Trial Group (ACTG)

(b) (6)

John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

(b) (6)

Elliot Levy, M.D.

Senior Vice President, Global Development
Amgen

(b) (6)

Lionel Bascles, Ph.D.

Senior Vice President, Global Head of Clinical Sciences & Operations
Sanofi

(b) (6)

Carlos Garner, Ph.D.

Vice President, Global Regulatory Affairs
Eli Lilly and Company

(b) (6)

Peter Stein, M.D.

Director of Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

(b) (6)

Beth Bell, M.D., MPH

Clinical Professor, Global Health
University of Washington

(b) (6)

Emilio Emini, Ph.D.

Director, TB & HIV Program
Bill & Melinda Gates Foundation

(b) (6)

Kathrin Jansen, Ph.D.

Senior Vice President and Head of Vaccine Research and Development
Pfizer

(b) (6)

Antonio Lanzavecchia, M.D.

Senior Vice President and Senior Research Fellow
Vir Biotechnology, Inc.
Director, Institute for Research in Biomedicine, Bellinzona, Switzerland

(b) (6)

Nancy Messonnier, M.D.

Director, Center for the National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

(b) (6)

Jonathan Seals, Ph.D.

Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority

(b) (6)

From: Myles, Renate (NIH/OD) [E] <(b) (6)>

Sent: Friday, May 15, 2020 7:53 AM

To: Collins, Francis (NIH/OD) [E] <(b) (6)>

Cc: Allen-Gifford, Patrice (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E]

<(b) (6)> ; Wooldridge, Shannon (NIH/OD) [E] <(b) (6)> Pollock, Rachel (NIH/OD) [E] <(b) (6)>

Subject: FW: Time sensitive: Making your ACTIV Participation Public

Hi Francis:

Below is the list of 23 vpeople who have not yet responded to your email. I cross referenced these names with the email list that Ashely sent and pulled addresses from that list. I didn't find emails for a number of these people, but I know there was a second round that went out using emails I don't have. Hoping Ashley can provide the missing emails.

(b) (6)

Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration

Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader
RTI International

Jay Grobler, Ph.D.

Director, Infectious Disease Biology
Merck & Co., Inc.

Cat Lutz, Ph.D.

Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center
The Jackson Laboratory

David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit
GlaxoSmithKline

Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases

Srinivas Rao, DVM, Ph.D.

Global Head, Translational In Vivo Models Global Research Platform
Sanofi

Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology
Director and Chief Academic Officer
Tulane University National Primate Research Center

Frank Stegmeier, Ph.D.

Chief Scientific Officer
KSQ Therapeutics

Sylva Collins, Ph.D.

Director, Office of Biostatistics
U.S. Food and Drug Administration

Judith Currier, M.D.

Professor of Medicine
University of California Los Angeles
Division of Infectious Diseases
Chair, AIDS Clinical Trial Group (ACTG)

(b) (6) u

John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

(b) (6)

Elliot Levy, M.D.

Senior Vice President, Global Development
Amgen

(b) (6)

Lionel Bascles, Ph.D.

Senior Vice President, Global Head of Clinical Sciences & Operations
Sanofi

(b) (6)

Carlos Garner, Ph.D.

Vice President, Global Regulatory Affairs
Eli Lilly and Company

(b) (6)

Peter Stein, M.D.

Director of Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

(b) (6)

Beth Bell, M.D., MPH

Clinical Professor, Global Health
University of Washington

Emilio Emini, Ph.D.

Director, TB & HIV Program
Bill & Melinda Gates Foundation

(b) (6)

Kathrin Jansen, Ph.D.

Senior Vice President and Head of Vaccine Research and Development
Pfizer

(b) (6)

Antonio Lanzavecchia, M.D.

Senior Vice President and Senior Research Fellow
Vir Biotechnology, Inc.
Director, Institute for Research in Biomedicine, Bellinzona, Switzerland

(b) (6)

Nancy Messonnier, M.D.

Director, Center for the National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

(b) (6)

Jonathan Seals, Ph.D.

Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority

From: Collins, Francis (NIH/OD) [E] (b) (6)

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Cc: Myles, Renate (NIH/OD) [E] <(b) (6)>; Meltzer, Abbey (FNIH) [T] (b) (6); Wholley, David (FNIH) [T] (b) (6) >

Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/2/2020 10:37:08 PM
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Subject: Follow-up to ACTIV-3 Operations Team Meeting
Attachments: INSIGHT014_ACTIV3_OperationalTeam_2June2020v2.pdf; ACTIV_Therapeutics-Clinical_Master Protocol Subgroup_ACTIV-3 Operations Team Meeting_20200602.pdf; ACTIV PPD NIH ACTIV2_SOW_20200601.docx

Dear ACTIV-3 Operations Team,

Please find attached the notes from today's call and the slides that Jens shared during the meeting. In addition, please find the operational needs checklist that Laura shared with the group. The INSIGHT team could use this to evaluate their needs as well for CROs.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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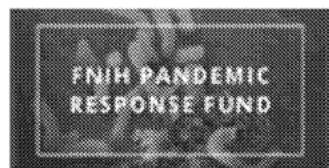
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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/22/2020 2:58:23 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [keith. (b) (6) Hughes, Eric [(b) (6) Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Amanda Peppercorn [(b) (6) Garner, Carl [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96c8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
(b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6)
Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [dana.carl (b) (6) Rose
Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas
Smalldon [(b) (6) Stratton, Benjamin [(b) (6)
(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]

Subject: ACTIV Therapeutics-Clinical Working Group - Meeting #4

Attachments: ACTIV Therapeutics-Clinical WG 30Apr2020 Agenda_v1.pdf; ACTIV Therapeutics-Clinical WG 30Apr2020 Meeting Guide.pdf

Location: <https://fnih.zoom.us/j/> (b) (6)

Start: 4/30/2020 6:00:00 PM

End: 4/30/2020 7:00:00 PM

Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]
Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]

Dear TX-Clinical WG Members,

Thank you so much for all your hard work this week. We are looking forward to have both subgroups update each other today.

Please find attached the materials for today's call.

1. Agenda
2. Slides

Thanks,
Stacey

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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 6/25/2020 1:38:12 PM
To: Bascles, Lionel [(b) (6)] Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6)] Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [(b) (6)] Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Garner, Carlos [(b) (6)] Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6)] Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [(b) (6)] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Takas, Therese [(b) (6)] Vincent, Mike [(b) (6)] Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]
CC: Wachtel, Jonathan [(b) (6)] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6)] Jansen, Kathrin [(b) (6)] Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)] Ardiffe, Bernadette [(b) (6)] Criffield, Robin [(b) (6)] Hamilton, Nancy [(b) (6)] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [(b) (6)] Mueller-Reichenstein, Petra [(b) (6)] Pico, Dianna (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora [(b) (6)] Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [(b) (6)] Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6)] James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kenny,

Dermot [dermot. (b) (6) Kublin, James [(b) (6) Li, Rose
[(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Santos, Michael (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveesson, Nancy
[(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting

Location: <https://fnih.zoom.us/> (b) (6)

Start: 7/28/2020 1:00:00 PM

End: 7/28/2020 2:00:00 PM

Show Time As: Tentative

Required Attendees: Bascles, Lionel; Cohen, Myron; Corey, Larry; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Garner, Carlos; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Mensah, George; Nayak, Seema (NIH/NIAID) [E]; Payton, Manzine; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Takas, Therese; Vincent, Mike; Weinmann, Gail

Optional Attendees: Wachtel, Jonathan; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Ardiffe, Bernadette; Criffiefield, Robin; Hamilton, Nancy; Melencio, Cheryl (FNIH) [T]; Minnich, Beth; Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] (b) (6) Zoe (NIH/NHLBI) Hill [C] (b) (6) Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E] (b) (6); Carluccio, Dana; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Kenny, Dermot; Kublin, James; Li, Rose; Menetski, Joseph (FNIH) [T]; Qashu, Felicia; Santos, Michael (FNIH); Tuveesson, Nancy; Wholley, David (FNIH) [T]

Dear Clinical Trial Capacity Working group members - As the tiger teams continue to work closely with ACTIV protocol development and operations teams, and the 'playbook' development teams ramp up to quickly develop these resources, we will reduce the number of times the full WG meets in July to every other week (July 14th and 28th). Best, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 6/8/2020 4:28:40 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Pao, William [(b) (6) Plump, Andrew [(b) (6) Stoffels, Paul [(b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [(b) (6) Anderson, Margaret [(b) (6) Chen, Helen [(b) (6) Elsaid, Olivia [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Ben [(b) (6) Tolman, Brett [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Perala, Mie [(b) (6) Protasiewicz, Ann [(b) (6) Riccobene, Kim [(b) (6) Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togashi, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Zottoli, Jessica

(b) (6) Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Hardesty, Rebecca (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]

Subject: ACTIV EC & Working Group Co-Chair Meeting

Location: <https://fnih.zoom>. (b) (6)

Start: 7/15/2020 7:00:00 PM

End: 7/15/2020 8:30:00 PM

Show Time As: Tentative

Required Attendees: Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John

Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Zottoli, Jessica; Sepulveda, Dorina (FNIH) [T]; Burklow, John (NIH/OD) [E]; Gorman, Greta (FNIH) [T]; Hallett,

Adrienne (NIH/OD) [E]; Meltzer, Abbey (FNIH) [T]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hardesty, Rebecca (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]

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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/7/2020 9:06:17 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6) Wung, Peter /US [(b) (6) Karen Lynn Price [(b) (6) Pamela Tenaerts, M.D. [(b) (6) Scott Berry [(b) (6) Angus, Derek [(b) (6) Meredith Buxton [(b) (6) Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Goffeney, Robertta [(b) (6)
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #17
Location: <https://fnih.zoom.us/> (b) (6)
Start: 5/15/2020 5:00:00 PM
End: 5/15/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butters; Collins, Sylvia (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Scott Berry; Angus, Derek; Meredith Buxton; Patterson, Amy (NIH/NHLBI) [E]

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Goffeney, Robertta

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/22/2020 1:27:42 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c289105913411a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6)
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US [(b) (6)
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #10
Location: <https://fnih.zoom.> (b) (6)
Start: 4/28/2020 5:00:00 PM
End: 4/28/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wung, Peter /US

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 6/17/2020 7:55:18 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [tomas.cihlar@gilead.com]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6) Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John [(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [(b) (6) Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aebc9a0d9b96c-NAR5]; Pangalos, Mene [(b) (6) Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Rasi, Guido [(b) (6) Reed, John [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [(b) (6) Tsai, John [(b) (6)]; Vessey, Rupert [(b) (6) Virgin, Skip [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin

[(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Castillejos, Carlos [(b) (6) Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Bancel, Stephane [(b) (6) Erck, Stan [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Lee, William [(b) (6) Paul, Steve [(b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [(b) (6) Anderson, Margaret [(b) (6) Chen, Helen [(b) (6) oelsaid [(b) (6) Gonzalez, Nina [(b) (6) Stratton, Ben [(b) (6) Tolman, Brett [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Togashi, Mieke (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Underwood, Nancy [(b) (6) Zottoli, Jessica [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Hardesty, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Edl, Susan [(b) (6) Giorgi, Sara [(b) (6) .eu]; Hoban, Michelle [(b) (6) Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter]; Iberdemaj, Vaide [(b) (6) McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Minnich, Beth [(b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann [(b) (6) Riccobene, Kim [(b) (6) Suhana, Tina (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=eb38a598f96f488299a655a7312138fd-gladmanjt]; FNIH Central Account [(b) (6) Ripley, Nadege [(b) (6) Riggan, Mary [(b) (6) Vessey, Rupert [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Hodes, Richard (NIH/NIA) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=265fd766498b41988e2ce55e8c6b5bc9-higginbotha]; Shapiro, Beth (NIH/NIDDK) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=0951d619e9bd411a9ae74582eeba6b5a-ashleysa]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=a1106941d5164156bf08e25f24057a4d-nvolkow]; Glass, Roger (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=e6e37ceffade4ea59375aab6fd35eb47-schulkeh]; Stover, Kathleen (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a372032e1b4999b57bc64b2e59304b-stoverka]; Hamid, Khawar (NIH/CSR) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=805b1f42695249cfb1b4243f7de59343-hamidkr]; Norris, Andrea (NIH/CIT) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1f8285333385410bb4be4ea63636d1d5-norrisat]; Wade, Portia (NIH/CIT) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=058d233dfb124f919afb5c20a0e79908-davispl2]; (b) (6) Anita Caulfield [(b) (6) Sharpless, Norman (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340f3d07b6644da7aca53ab83dc066ef-sharplessne]; Bianchi, Diana (NIH/NICHD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e701b633c0214cb887a00d28a48e19d3-bianchidw]; Ott, Sandra (NIH/NICHD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fdd4311f07342f5af65c48cd1b53412-otts]; Ramirez, Katherine (NIH/NIMHD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e25b98237bb41e3adccbe7a4dd2b6ca-ramirez]; Perez-Stable, Eliseo (NIH/NIMHD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06f5c7aad094f6685d9f1d260d46441-perezstable]; Council, Lisa (NIH/NCCIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=46e1791d0feb4292b43f48a40f4934e1-dixonlr]; Langevin, Helene (NIH/NCCIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbb10311b6e0462b970030434fe0e21b-langevinhm]; Schwetz, Tara (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b1da1e9650d44fa9a9e2d94f24b5035-schwetzta]; Dzokoto-Pomenya, Caroline (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f96013017dd4c409ccb21fe454d0f00-dzokotoc]

Subject: ACTIV Leadership Call #6

Attachments: RE: Materials for July 29 ACTIV Executive Committee Teleconference; Materials for July 29 ACTIV Executive Committee Teleconference; ACTIV LT meeting notes July 29 2020.docx

Location: <https://fnih.zoom.> (b) (6)

Start: 7/29/2020 6:30:00 PM

End: 7/29/2020 8:00:00 PM

Show Time As: Busy

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lee, William; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmuter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Bancel, Stephane; Erck, Stan

Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hardesty, Rebecca (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; FNIH Central Account; Ripley, Nadege; Riggan, Mary; Vessey, Rupert; Lowy, Douglas (NIH/NCI) [E]; Gorman, Greta (FNIH) [T]; Lucas Smalldon; Klote, Mary (Molly); Victoria Davey; Hodes, Richard (NIH/NIA) [E]; Bronson, Charlette (NIH/NIA) [E]; Best, Cindy (NIH/NEI) [E]; Tumminia, Santa (NIH/NEI) [E]; Meltzer, Abbey (FNIH) [T]; Koroshetz, Walter (NIH/NINDS) [E]; Koob, George (NIH/NIAAA) [E]; Rodgers, Griffin (NIH/NIDDK) [E]; Woychik, Rick (NIH/NEHS) [E]; Higginbotham, Aurelia (NIH/NIAAA) [E]; Shapiro, Beth (NIH/NIDDK) [E]; Eason, Allison (NIH/NEHS) [E]; Walker, Paula (NIH/NINDS) [E];

Volkow, Nora (NIH/NIDA) [E]; Glass, Roger (NIH/FIC) [E]; Tucci, Debara (NIH/NIDCD) [E]; Byrnes, Noni (NIH/CSR) [E]; Schulke, Hilda (NIH/NIDA) [E]; Stover, Kathleen (NIH/FIC) [E]; Hamid, Khawar (NIH/CSR) [E]; Norris, Andrea (NIH/CIT) [E]; Wade, Portia (NIH/CIT) [E]; (b) (6) Anita Caulfield; Sharpless, Norman (NIH/NCI) [E]; Bianchi, Diana (NIH/NICHD) [E]; Ott, Sandra (NIH/NICHD) [E]; Ramirez, Katherine (NIH/NIMHD) [C]; Perez-Stable, Eliseo (NIH/NIMHD) [E]; Council, Lisa (NIH/NCCIH) [E]; Langevin, Helene (NIH/NCCIH) [E]; Schwetz, Tara (NIH/OD) [E]; Dzokoto-Pomenya, Caroline (NIH/OD) [C]

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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Jim Neaton [(b) (6) Jens Lundgren [(b) (6) Eric Hughes [(b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Karen Lynn Price [(b) (6) LaVange, Lisa M [(b) (6) Sandeep Menon [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80023e7be2dd4554b54d1604fa60df18-rachel.h.ha]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; [(b) (6) Gelijns, Annetine [(b) (6) Moskowitz, Alan [(b) (6) Ab Babiker [(b) (6) Cavan, Reilly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=995fe0f1a53c443a832f96f003f0f2c5-cavanr.bios]; Phillips, Andrew [(b) (6)]; Birgit Grund [(b) (6) Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f2b26b051964d9da6868e53c9cc6c49-jim.cabr.um]; Joe Koopmeiners [(b) (6) David Vock [(b) (6) Thomas Murray [(b) (6) Max Parmar [(b) (6) Mark Polizzotto [(b) (6) Ginny Kan [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Baker, Jason [(b) (6) Roger Paredes [(b) (6) [(b) (6) [(b) (6) M [(b) (6) [(b) (6) Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; [(b) (6) [(b) (6) Ajay Nirula [(b) (6) Paul Klekotka [(b) (6) Ginde, Adit [(b) (6) [(b) (6)]
CC: Demarcus [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chen, Helen Q. [(b) (6) Eron, Joseph J Jr [(b) (6) Chew, Kara M.D. [(b) (6) Daar, Eric [(b) (6) Bagiella, Emilia [(b) (6) [(b) (6) Lisbeth Jørgensen [lisbeth. [(b) (6) Erhardt, William (HHS/IOS) [(b) (6)]
Subject: ACTIV-3 Writing Team Meeting
Attachments: ACTIV_TX-Clinical_ACTIV-3 Writing Team Meeting Agenda_20200622.pdf
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(b) (6) Gelijns, Annetine; Moskowitz, Alan; Ab Babiker; Cavan, Reilly; Phillips, Andrew
(b) (6) Birgit Grund; Neaton, Jim; Joe Koopmeiners; David Vock; Thomas Murray; Max Parmar; Mark Polizzotto; Ginny Kan; Lane, Cliff (NIH/NIAID) [E]; Baker, Jason; Roger Paredes; (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6) Rosenberg, Yves (NIH/NHLBI) [E]; (b) (6) (b) (6) Ajay Nirula; Paul Klekotka; Ginde, Adit
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Parker, Ashley (NIH/OD) [E]; Chen, Helen Q.; Eron, Joseph J Jr; Chew, Kara M.D.; Daar, Eric; Bagiella, Emilia; chip-activ3-insight014.rigshospitalet@regionh.dk; Lisbeth Jørgensen; Erhardt, William (HHS/IOS)

Dear ACTIV-3 Writing Team,

Please see a high level agenda for today's call.

Thanks,
Stacey

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Sent: 6/17/2020 7:55:15 PM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) .eu]; Cihlar, Tomas [tomas.cihlar@gilead.com]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6) Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lee, William [(b) (6) Lepore, John [(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh [(b) (6) Pangalos, Mene [(b) (6) Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Rasi, Guido [(b) (6) Reed, John [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [(b) (6) Tsai, John [(b) (6) Vessey, Rupert [(b) (6) m]; Virgin, Skip [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy

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 (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Elsaid, Olivia [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange
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 (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Giorgi, Sara [(b) (6) Hoban, Michelle [(b) (6)
 Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative
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 [(b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann
 [(b) (6) Riccobene, Kim [(b) (6) Sepulveda, Dorina (FNIH) [T]
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 (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burklow, John
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Hallett, Adrienne (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Myles, Renate (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolinetz, Carrie (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Hardesty, Rebecca
 (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]; Gorman, Greta (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Meltzer, Abbey (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Togashi, Mieko (NIH/NCI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Underwood, Nancy
[(b) (6) Zottoli, Jessica | (b) (6)

Subject: ACTIV Leadership Call #6

Location: <https://fnih.zoom.> (b) (6)

Start: 7/29/2020 6:30:00 PM

End: 7/29/2020 8:00:00 PM

Show Time As: Tentative

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lee, William; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]

Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Hardesty, Rebecca (NIH/OD) [C]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 8/7/2020 12:59:54 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [naimish. Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Amanda Peppercorn [(b) (6) Garner, Carl [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96c8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore] CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas Smalldon [(b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; (b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [(b) (6) Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]

Subject: ACTIV Therapeutics-Clinical Working Group Meeting

Location: <https://fnih.zoom.us/> (b) (6)

Start: 6/25/2020 5:00:00 PM

End: 6/25/2020 6:00:00 PM

Show Time As: Tentative

Recurrence: Weekly

every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6); Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6); Sizemore, Christine (NIH/FIC) [E]

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6); Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6)

Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla
 [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6)
 Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6) Rose
 Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas
 Smalldon [(b) (6) Stratton, Benjamin [(b) (6)
 (b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Goff, David (NIH/NHLBI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Rubin, Daniel B. (FDA/CDER)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: ACTIV TX-Clinical Working Group Meeting #8

Location: [\(b\) \(6\)](https://fnih.zoom.us/j/ (b) (6))

Start: 5/28/2020 5:00:00 PM

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Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] ((b) (6) Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]

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CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Rose Li Central Account [(b) (6) Lucas Smalldon [(b) (6) Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US [(b) (6)
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #4
Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_21Apr2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical Master Protocol Sub-Group Meeting Agenda_04212020.pdf; D. Goff network capacity template_04202020.xlsx; ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 3_Key Takeaways_04202020.pdf
Location: https://fnih.zoom. (b) (6)
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Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butters; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Rose Li Central Account; Lucas Smalldon; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wung, Peter /US

Dear ACTIV TX-Clinical Master Protocol SG,

Please find attached the materials for today's call. Apologies for the slight delay in sending.

1. Agenda
2. Slides for Discussion – Updated Timelines for feedback and then questions to consider for the two master protocols to start deciding design.
3. Clinical Trial Network Survey – the CTC WG would like any feedback we might have about other needed information.
4. High level update from yesterday

We look forward to speaking with you today.

Thanks,
Stacey

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CC: DeMarcus, Forrest [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jhoanna Roa [(b) (6) Smith, David [(b) (6) Paul Klekotka [(b) (6) Ajay Nirula [(b) (6) Elsaid, Olivia [(b) (6) Robert Jan Benschoep [(b) (6) Lei Shen [(b) (6)]
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Here is my question for the group – especially Michael, John and Lisa

My question is whether there could be an interim “activity” analysis similar to the futility analysis listed below – the reason I ask is we have very little longitudinal data on the quantitative viral shedding and it is possible that this endpoint would have substantial power such that 50 patients per arm could provide an antiviral answer.

- If the Phase 2 portion of the Clinical mAb protocol is used for dose finding, this may be challenging with respect to size of the trial (number of treatment arms needed and available sample size per treatment arm). In addition, it may be appropriate to establish an interim futility analysis based on change in quantitative viral shedding to allow for discontinuation of a dose after e.g. 50 rather than 110 patients, or to allow early discontinuation of high doses due to safety findings.

Joe Eron MD
Professor of Medicine
University of North Carolina at Chapel Hill

APAR0000005346-2517818

School of Medicine
(b) (6)

From: Adam, Stacey (FNIH) [T] <(b) (6)>

Sent: Wednesday, May 20, 2020 5:42 PM

To: Judy Currier <(b) (6)> Eric Hughes <(b) (6)> LaVange, Lisa M
<(b) (6)> Sandeep Menon <(b) (6)> Proschan, Michael (NIH/NIAID) [E]
<(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Price, Dionne (FDA/CDER)
<(b) (6)> Rubin, Daniel B. (FDA/CDER) <(b) (6)> Farley, John (FDA/CDER)
<(b) (6)> Karen Lynn Price <(b) (6)> (b) (6)
(b) (6) (b) (6) (b) (6) Wohl, David A
<(b) (6)> Fischer, William A. II <(b) (6)> Eron, Joseph J Jr
<(b) (6)> Javan, Arzhang (NIH/NIAID) [E] <(b) (6)> Roa, Jhoanna <jroa@s-
3.com>; (b) (6) Kim, Peter (NIH/NIAID) [E] <(b) (6)> Jonathan Li <(b) (6)>
Marks, Gilbert (OS/ASPR/BARDA) (CTR) <(b) (6)> Kozak, Marina (OS/ASPR/BARDA)
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Cc: DeMarcus, Forrest <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan
<(b) (6)> Elizabeth Kim <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>
Jhoanna Roa <(b) (6)> Eron, Joseph J Jr <(b) (6)> Smith, David
<(b) (6)> Paul Klekotka <(b) (6)> Ajay Nirula <(b) (6)> Elsaid,
Olivia <(b) (6)> Robert Jan Benschop <(b) (6)> Lei Shen <(b) (6)>
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Dear mAb Outpatient WT,

The FDA team that has been working with ACTIV and sitting in on our writing team meetings for this protocol would like to offer the attached thoughts for the group's consideration on tonight's call.

Also, attaching again the updated synopsis that was discussed with the mAb Steering Committee earlier today.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
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To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Mellors, John W (b) (6) Proschan, Michael (NIH/NIAID) [E] (b) (6) Read, Sarah (NIH/NIAID) [E] (b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roisenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Levy, Elliot (b) (6) Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra (b) (6) Eisner, Mark (b) (6) Gottesdiener, Keith (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Amanda Peppercorn [(b) (6) Garner, Carl [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Tountas, Karen (FNIH) [T]

CC:

[/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Tolman, Brett
 [(b) (6) Alvarez, Rosa [(b) (6) Gonzalez, Nina [(b) (6)
 Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Stratton, Benjamin
 [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B.
 (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Elsaid, Olivia
 [(b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acb5fd03b3cf32930-walkerp1]; Colvis, Christine
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
 [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John
 (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6)
 Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla
 [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
 (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Gonzalez, Nina
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana
 Carluccio [(b) (6) Rose Li Central Account [(b) (6) Margaret
 Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Lucas Smalldon
 [(b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; (b) (6) Mollica, Linda /US
 (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B.
 (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerpl]; Bethany Stokes [(b) (6) Sorosa, Alex David [(b) (6)

Subject: Canceled: ACTIV Therapeutics-Clinical Working Group Meeting

Start: 11/26/2020 6:00:00 PM

End: 11/26/2020 7:00:00 PM

Show Time As: Free

Recurrence: (none)

Required Attendees: Levy, Elliot; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]

Dear ACTIV TX-Clinical WG Members,

Cancelling this last Thursday in November due to Thanksgiving!

Thanks,
Stacey

Join Zoom Meeting
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US (Houston)
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(b) (6) US (San Jose)

Meeting ID: (b) (6)

Password: (b) (6)

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/18/2020 1:58:33 PM
To: Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Thanks!!

From: Wooldridge, Shannon (NIH/OD) [E] <(b) (6)>
Sent: Monday, May 18, 2020 9:17 AM
To: Myles, Renate (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Pollock, Rachel (NIH/OD) [E] <(b) (6)>
Subject: RE: Time sensitive: Making your ACTIV Participation Public

No replies from Baric, Deming, or Jansen in FC's inbox. I just ran a search.

From: Myles, Renate (NIH/OD) [E] <(b) (6)>
Sent: Monday, May 18, 2020 9:16 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6)>; Pollock, Rachel (NIH/OD) [E] <(b) (6)>; Wooldridge, Shannon (NIH/OD) [E] <(b) (6)>
Subject: RE: Time sensitive: Making your ACTIV Participation Public
Importance: High

Hi Rachel and Shannon:

Would you check FC's mailbox for this information ASAP? We need to launch the webpage this morning.

Thanks,
Renate

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Monday, May 18, 2020 7:57 AM
To: Myles, Renate (NIH/OD) [E] <(b) (6)> Pollock, Rachel (NIH/OD) [E] <(b) (6)> Wooldridge, Shannon (NIH/OD) [E] <(b) (6)>
Subject: Re: Time sensitive: Making your ACTIV Participation Public

Hi Renate, Rachel, and Shannon,

We've made lots of progress! Shannon — can we see if the 3 ACTIV participants responded to Dr. Collins privately over the weekend?

Thank you,
Ashley

On May 17, 2020, at 11:15 PM, Myles, Renate (NIH/OD) [E] <(b) (6)> wrote:

Hi Ashley and Rachel:

Below are the three people I did not hear from. I searched my inbox. Just wanted to double check that they didn't just respond to Francis. Thanks, Renate

Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

(b) (6)

Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration

(b) (6)

Kathrin Jansen, Ph.D.

Senior Vice President and Head of Vaccine Research and Development
Pfizer

(b) (6)

From: Collins, Francis (NIH/OD) [E] (b) (6)

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Cc: Myles, Renate (NIH/OD) [E] <(b) (6)>; Meltzer, Abbey (FNIH) [T] <(b) (6)>

Wholley, David (FNIH) [T] (b) (6)

Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Tomas Cihlar [(b) (6)]
Sent: 7/1/2020 6:14:09 PM
To: Rappaport, Jay (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)
(b) (6) : (b) (6) (b) (6) (b) (6) Baric, Ralph
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp];
(b) (6) (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria

[(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel,
Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Rose Li
[(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
[(b) (6) Dave Frankowski [(b) (6) Baric, Toni C
[(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nancy Haigwood
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
[(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm];
(b) (6) Diamond, Michael [(b) (6)

Subject: RE: ACTIV Preclinical full working group

Dear all,

Apologies if I state something obvious that has been discussed during today ACTIV meeting as I have been simultaneously listening to the WHO COVID forum and might have missed it.

The point I want to make is about analysis of genetic changes in the CoV2 virus over time. D614G is only one example that caught peoples eye since the prevalence is so obvious now, but other changes in other proteins of the virus might be happening that could potentially be relevant for sensitivity to new drugs that we are/will be triaging. As of now there are more than 50,000 sequences available in public databases worldwide.

My question is whether there would be interest in monitoring CoV2 sequences over time with a focus on genes most relevant as antiviral targets. Gilead has built infrastructure to do this effectively, initially for nsp12 gene because of remdesivir, but we then expanded to some of the other CoV2 genes and through that we first noticed D614G as early as in mid March long before it became highly prevalent. If there is interest, I'd be happy to discuss the genotypic monitoring at one of the future calls.

Thank you,

Tomas

Tomas Cihlar, PhD

Vice President, Virology

Gilead Sciences, Inc.

Office: (b) (6)

Email:

From: Rappaport, Jay < (b) (6) >

Sent: Wednesday, July 01, 2020 8:51 AM

To: Punturieri, Antonello (NIH/NHLBI) [E] < (b) (6) > Florence, Clint (NIH/NIAID) [E]

< (b) (6) > Menetski, Joseph (FNIH) [T] < (b) (6) > Hild, Sheri (NIH/OD) [E]

< (b) (6) > (b) (6) < (b) (6) > (b) (6)

(b) (6) (b) (6) Baric, Ralph < (b) (6) > (b) (6) Ottinger,

Elizabeth (NIH/NCATS) [E] < (b) (6) > Colvis, Christine (NIH/NCATS) [E] < (b) (6) >

Hewitt, Judith (NIH/NIAID) [E] < (b) (6) > Deming, Damon (FDA/CDER) < (b) (6) >

(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Collins, Francis
(NIH/OD) [E] < (b) (6) (b) (6) Adams, Peter (OS/ASPR/BARDA)
< (b) (6) Rao, Srinivas < (b) (6) Qashu, Felicia (NIH/OD) [E]
< (b) (6) Tomas Cihlar < (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID
(USA) < (b) (6) Charette, Marc (NIH/NHLBI) [E] < (b) (6) Fessel, Josh
(NIH/NHLBI) [E] < (b) (6) (b) (6) (b) (6) Wholley, David (FNIH)
[T] < (b) (6) Austin, Christopher (NIH/NCATS) [E] < (b) (6) Melencio, Cheryl (FNIH) [T]
< (b) (6) Colvis, Christine (NIH/NCATS) [E] < (b) (6) Desrosiers, Betsy
< (b) (6) Hughes, Eric < (b) (6) Jansen, Kathrin
< (b) (6) Kurilla, Michael (NIH/NCATS) [E] < michael. (b) (6) Lowy, Douglas (NCI)
< (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6)
Santos, Michael (FNIH) [T] < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) James, Stephanie (FNIH)
[T] < (b) (6) Alvarez, Rosa Maria < (b) (6) Kim, Elizabeth < (b) (6) Tolman,
Brett < (b) (6) Wachtel, Jonathan < (b) (6) Prabhavathi Fernandes
< (b) (6) Rose Li < (b) (6) Dana Carluccio
< (b) (6) Lagos, Enrique (NIH/NCATS) [E] < (b) (6) Jonson, Samantha
(NIH/NCATS) [E] < (b) (6) Gonzalez, Nina < (b) (6) Simon, Dina (NIH/OD) [C]
< (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] < (b) (6) Rodriguez, Robin D
< (b) (6) Dave Frankowski < (b) (6) Baric, Toni C
< (b) (6) Lowy, Douglas (NIH/NCI) [E] < (b) (6) Nancy Haigwood
< (b) (6) Stratton, Benjamin < (b) (6) Gadbois, Ellen (NIH/OD) [E]
< (b) (6) Anderson, James (NIH/OD) [E] < (b) (6) (b) (6)
Diamond, Michael < (b) (6)

Subject: [EXTERNAL] Re: ACTIV Preclinical full working group

Clint and Tony, thanks, important observations.

Best,
Jay

From: "Punturieri, Antonello (NIH/NHLBI) [E]" < (b) (6) >

Date: Wednesday, July 1, 2020 at 10:43 AM

To: "Florence, Clint (NIH/NIAID) [E]" < (b) (6) >, "Menetski, Joseph (FNIH) [T]"

< (b) (6) >, "Hild, Sheri (NIH/OD) [E]" < (b) (6) >, " (b) (6) "

< (b) (6) >, " (b) (6) " < (b) (6) >, "Rappaport, Jay"

< (b) (6) >, " (b) (6) " < (b) (6) >, " (b) (6) "

< (b) (6) >, " (b) (6) " < (b) (6) >, "Baric, Ralph" < (b) (6) >

< (b) (6) >, "Ottinger, Elizabeth (NIH/NCATS) [E]"

< (b) (6) >, "Colvis, Christine (NIH/NCATS) [E]" < (b) (6) >, "Hewitt, Judith

(NIH/NIAID) [E]" < (b) (6) >, "Deming, Damon (FDA/CDER)" < (b) (6) >

" (b) (6) " < (b) (6) >, " (b) (6) " < (b) (6) >, "Parker,

Ashley (NIH/OD) [E]" < (b) (6) >, "Collins, Francis (NIH/OD) [E]" < (b) (6) > ,

" (b) (6) >, "Adams, Peter (OS/ASPR/BARDA)"

< (b) (6) >, "Rao, Srinivas" < (b) (6) >, "Qashu, Felicia (NIH/OD) [E]"

< (b) (6) >, Tomas Cihlar < (b) (6) >, "Pitt, Margaret L CIV USARMY MEDCOM

USAMRIID (USA)" < (b) (6) >, "Charette, Marc (NIH/NHLBI) [E]" < (b) (6) >

"Fessel, Josh (NIH/NHLBI) [E]" < (b) (6) >

< (b) (6) >, " (b) (6) " < (b) (6) >, "Wholley, David

(FNIH) [T]" < (b) (6) >, "Austin, Christopher (NIH/NCATS) [E]" < (b) (6) >, "Melencio,

Cheryl (FNIH) [T]" < (b) (6) >, "Colvis, Christine (NIH/NCATS) [E]" < (b) (6) >

"Desrosiers, Betsy" < elizabeth (b) (6) >, "Hughes, Eric" < eric.hughes@novartis.com >, "Jansen,

Kathrin" < (b) (6) >, "Kurilla, Michael (NIH/NCATS) [E]" < (b) (6) >, "Lowy,

Douglas (NCI)" (b) (6) , "Read, Sarah (NIH/NIAID) [E]" (b) (6) >, "Tountas, Karen (FNIH) [T]" (b) (6) >, "Santos, Michael (FNIH) [T]" (b) (6) >, "Adam, Stacey (FNIH) [T]" (b) (6) >, "James, Stephanie (FNIH) [T]" < (b) (6) "Alvarez, Rosa Maria" (b) (6) >, "Kim, Elizabeth" (b) (6) >, "Tolman, Brett" < (b) (6) "Wachtel, Jonathan" (b) (6) >, Prabhavathi Fernandes < (b) (6) Rose Li (b) (6) >, Dana Carluccio < (b) (6) "Lagos, Enrique (NIH/NCATS) [E]" < (b) (6) "Jonson, Samantha (NIH/NCATS) [E]" < (b) (6) "Gonzalez, Nina" (b) (6) "Simon, Dina (NIH/OD) [C]" (b) (6) "Burrus-Shaw, Cyndi (NIH/OD) [E]" (b) (6) "Rodriguez, Robin D" (b) (6) Dave Frankowski < (b) (6) "Baric, Toni C" (b) (6) >, "Lowy, Douglas (NIH/NCI) [E]" (b) (6) Nancy Haigwood (b) (6) >, "Stratton, Benjamin" < (b) (6) >, "Gadbois, Ellen (NIH/OD) [E]" (b) (6) "Anderson, James (NIH/OD) [E]" (b) (6) (b) (6) (b) (6) (b) (6) >, "Diamond, Michael" < (b) (6)

Subject: RE: ACTIV Preclinical full working group

External Sender. Be aware of links, attachments and requests.

And convalescent plasma appears to block it as well as the G variant

Tony

From: Florence, Clint (NIH/NIAID) [E] (b) (6)
Sent: Wednesday, July 1, 2020 11:39 AM
To: Menetski, Joseph (FNIH) [T] (b) (6) Hild, Sheri (NIH/OD) [E] (b) (6) ; (b) (6) ; Baric, Ralph (b) (6) ; Ottinger, Elizabeth (NIH/NCATS) [E] < (b) (6) Colvis, Christine (NIH/NCATS) [E] (b) (6) ; Hewitt, Judith (NIH/NIAID) [E] (b) (6) Deming, Damon (FDA/CDER) < (b) (6) ; Parker, Ashley (NIH/OD) [E] < (b) (6) ; Collins, Francis (NIH/OD) [E] (b) (6) ; Adams, Peter (OS/ASPR/BARDA) (b) (6) ; Rao, Srinivas (b) (6) ; Qashu, Felicia (NIH/OD) [E] Tomas Cihlar < (b) (6) ; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) < (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] (b) (6) >; Charette, Marc (NIH/NHLBI) [E] (b) (6) Fessel, Josh (NIH/NHLBI) [E] < (b) (6) ; Wholley, David (FNIH) [T] (b) (6) ; Austin, Christopher (NIH/NCATS) [E] < (b) (6) Melencio, Cheryl (FNIH) [T] < (b) (6) Colvis, Christine (NIH/NCATS) [E] < (b) (6) Desrosiers, Betsy (b) (6) >; Hughes, Eric (b) (6) ; Jansen, Kathrin < (b) (6) ; Kurilla, Michael (NIH/NCATS) [E] (b) (6) Lowy, Douglas (NCI) < (b) (6) Read, Sarah (NIH/NIAID) [E] (b) (6) Tountas, Karen (FNIH) [T] (b) (6) >; Santos, Michael (FNIH) [T] (b) (6) >; Adam, Stacey (FNIH) [T] (b) (6) ; James, Stephanie (FNIH) [T] (b) (6) >; Alvarez, Rosa Maria < (b) (6) Kim, Elizabeth (b) (6) >; Tolman, Brett (b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes (b) (6) >; Rose Li (b) (6) ; Dana Carluccio (b) (6) >; Lagos, Enrique (NIH/NCATS) [E] (b) (6) >; Jonson, Samantha (NIH/NCATS) [E] < (b) (6) >; Gonzalez, Nina (b) (6) Simon, Dina (NIH/OD) [C] (b) (6) >; Burrus-Shaw, Cyndi (NIH/OD) [E] (b) (6) Rodriguez, Robin D (b) (6) >; Dave Frankowski < (b) (6) Baric, Toni C (b) (6) ; Lowy, Douglas (NIH/NCI) [E] (b) (6) ; Florence, Clint (NIH/NIAID) [E] (b) (6) ; Nancy Haigwood

(b) (6); Stratton, Benjamin <(b) (6)>; Gadbois, Ellen (NIH/OD) [E]
>; Anderson, James (NIH/OD) [E] (b) (6)
Diamond, Michael <(b) (6)>
Subject: Re: ACTIV Preclinical full working group

All –

U PITT's pre-print in YOUNG AGMs utilizes the Munich strain which I believe has the D614 mutant.

In their hands, they didn't report any dramatic increase in pathogenesis with the assays they implemented.

Might be of benefit in the EXE meeting tonight.

Just an FYI.

Clint

From: (b) (6)
When: 10:00 AM - 11:00 AM July 1, 2020
Subject: ACTIV Preclinical full working group
Location: <https://fnih.zoom.us> (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
<https://fnih.zoom.us> (b) (6)

Meeting ID: (b) (6)
Password: (b) (6)
One tap mobile
(b) (6) US (Germantown)
US (Chicago)

Dial by your location
(b) (6) US (Germantown)
US (Chicago)
US (New York)
US (San Jose)
US (San Jose)
US (Tacoma)
US (Houston)

Meeting ID: (b) (6)
Password: (b) (6)
Find your local number: <https://fnih.zoom.us> (b) (6)

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/8/2020 3:59:15 AM
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CC: Demarcus [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chen, Helen Q. [(b) (6)]; Eron, Joseph J Jr [(b) (6)]; Chew, Kara M.D. [(b) (6)]; Daar, Eric [(b) (6)]; Bagiella, Emilia [(b) (6)]
Subject: ACTIV-3 Writing Team Meeting
Attachments: ACTIV_TX-Clinical_ACTIV-3 Writing Team Meeting Agenda_20200608.pdf
Location: <https://fnih.zoom.us/j> (b) (6)
Start: 6/8/2020 3:00:00 PM
End: 6/8/2020 4:00:00 PM
Show Time As: Tentative

Required Attendees: Jim Neaton; Jens Lundgren; Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA); Patterson, Amy (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Reineck, Lora (NIH/NHLBI) [E]; Judy Currier; Karen Lynn Price; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; William Erhardt; (b) (6) Gelijns, Annetine; Moskowitz, Alan; Ab Babiker; Cavan, Reilly; Phillips, Andrew (b) (6) Birgit Grund; Neaton, Jim; Joe Koopmeiners; David Vock; Thomas Murray; Max Parmar; Mark Polizzotto; Ginny Kan; Lane, Cliff (NIH/NIAID) [E]; Baker, Jason; Roger Paredes; (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) Rosenberg, Yves (NIH/NHLBI) [E]; (b) (6)
(b) (6) Ajay Nirula; Paul Klekotka

Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Parker, Ashley (NIH/OD) [E]; Chen, Helen Q.; Eron, Joseph J Jr; Chew, Kara M.D.; Daar, Eric; Bagiella, Emilia

Monday, June 8, 2020 – 11-12pm ET

Dear ACTIV-3 Writing Team,

Please find attached the agenda for tomorrow's call. I will distribute any other materials for the meeting in the morning.

Thanks,

Stacey

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To: Bascles, Lionel [(b) (6)] Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6)] Desrosiers, Betsy [(b) (6)] Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King.]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6)] Srinivasan, Badhri [(b) (6)] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [(b) (6)] Wachtel, Jonathan [(b) (6)]; Garner, Carlos [(b) (6)] Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6)] Jansen, Kathrin [(b) (6)] Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)] Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6)] Carluccio, Dana [(b) (6)] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6)] James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6)] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [(b) (6)] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [(b) (6)] Hamilton, Nancy [(b) (6)] Minnich, Beth [(b) (6)] Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Stratton, Benjamin [(b) (6)] Tolman, Brett [(b) (6)] Kenny, Dermot [(b) (6)]

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 Emi (b) (6) (b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc];
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 Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccba4e3caaf5eb5d3586b1cc-Jonathan.Se];
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 (b) (6) (b) (6) (b) (6) (b) (6)
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Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05122020.pdf
Location: https://zoom.us/j, (b) (6)

Start: 5/12/2020 3:00:00 PM
End: 5/12/2020 4:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
 every Tuesday and Friday from 9:00 AM to 10:00 AM

Required Attendees: Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; King, James; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzone; Resnansky, Laura; Srinivasan, Badhri; Stein, Peter (FDA/CBER); Vincent, Mike; Wachtel, Jonathan; Garner, Carlos; Sizemore, Christine (NIH/FIC) [E]; Qashu, Felicia

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T]
 (b) (6) Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] (b) (6); Stratton, Benjamin; Tolman, Brett; Kenny, Dermot; (b) (6) (b) (6) (b) (6)
 (b) (6) (b) (6) Haynes, Barton; (b) (6)
 (b) (6) Lowy, Douglas (NIH/NCI) [E]; Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];

Messonnier, Nancy (CDC/DDID/NCIRD/OD); (b) (6) Offit, Paul; (b) (6) Seals,
Jonathan (OS/ASPR/BARDA); (b) (6) (b) (6) Arvin, Ann; (b) (6)
(b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) Jessica. (b) (6) Johnson, Maureen
(NIH/NCI) [E]; Kozlowski, Mary (NIH/NCI) [C]; Austin, Sarah (NIH/NIAID) [E]; Davey, Victoria; Jintanat Ananworanich;
Michael Watson (x); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Schrag, Stephanie (CDC/DDID/NCIRD/DBD);
Marovich, Mary (NIH/NIAID) [E]

Apologies for the repeat emails, updated agenda is attached. Karen

Dear Colleagues, Attached is the meeting agenda. Looking forward to a robust discussion about vaccine protocols and capacity needs! Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Sandeep Menon [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proschan]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [(b) (6) (b) (6) (b) (6) (b) (6) (b) (6) william_fischer@med.unc.edu; Eron, Joe (b) (6) Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; (b) (6) Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC: Demarcus [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [(b) (6) Eron, Joseph J Jr [(b) (6) Smith, David [(b) (6) Paul Klekotka [(b) (6) Ajay Nirula [(b) (6) Chen, Helen Q. [(b) (6)]
Subject: Follow-up on ACTIV-2 Writing Team Meeting
Attachments: ACTIV_Therapeutics-Clinical_Master Protocol Subgroup_ACTIV-2 Writing Team Meeting_20200528.pdf; 2020-05-27_TX-Clinical_WG_ACTIV-2_Writing Team_mAb_SC_Summary.pdf

Dear ACTIV-2 Writing Team,

Thank you all for a very productive meeting. I think we are making good head way on the protocol. Looking forward to sharing it with the companies and FDA next week for feedback.

Please find the notes from the meeting today. If you have any additions or amendments, let us know. In addition, please find the summary of the joint meeting with the mAb Steering Committee from yesterday. Take note of the minimal data that FDA mentions for entering Phase 2. I thought John's take was helpful.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health

APAR0000005260-2517825

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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/15/2020 7:21:22 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Vincent, Michael [(b) (6) Wung, Peter /US [(b) (6) Karen Lynn Price [(b) (6) Pamela Tenaerts, M.D. [(b) (6) Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy [(b) (6) Beumont-Mauviel, Maria [JRDUS] [(b) (6) Peeters, Monika [JRDBE] [(b) (6) Woodfall, Brian [JRDUS] [(b) (6) Van Heeswijk, Rolf [JRDBE] [(b) (6) Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Bharucha_David [(b) (6) Gavin, Brian [(b) (6) Sadeh, Jonathan [(b) (6) Harler, Mary Beth [(b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Melsheimer, Rich [CNTNL] [(b) (6)]

Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #20

Attachments: ACTIV_Therapeutics Clinical Master Protocol Sub Group_22May2020 Meeting Guide.pdf; Agenda capture 1.PNG

Location: <https://fnih.zoom.us/> (b) (6)

Start: 5/22/2020 6:00:00 PM

End: 5/22/2020 6:30:00 PM

Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters, Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]; Brown, Jeremy (NIH/NINDS) [E]; Bharucha, David; Gavin, Brian; Sadeh, Jonathan; Harler, Mary Beth

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Melsheimer, Rich [CNTNL]

Dear ACTIV TX-Clinical Master Protocol Subgroup,

For this meeting today, we have decide to split this meeting into two meetings to make most efficient use of everyone's time. This first 30 minute meeting will be the entire group with the companies for ACTIV-1 to discuss the next steps for this protocol. The second 30 minutes will now become a meeting of the mAb Steering Committee to finalize some decisions for the ACTIV-2 protocol that need to be completed by EOD today.

Thanks for your understanding.

Please find attached the slides for this first meeting today.

Thanks, Stacey

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
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CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]
Subject: Daily ACTIV Calls
Attachments: Canceled: Daily ACTIV Calls; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment
Location: Dial-in: (b) (6) Passcode: (b) (6)
Start: 5/6/2020 12:00:00 PM
End: 5/6/2020 12:30:00 PM
Show Time As: Busy
Recurrence: Weekly
every Wednesday from 8:00 AM to 8:30 AM
Required Attendees: Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Freire, Maria (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Carver, Trea (NIH) [C]
Dial-in: (b) (6)
Passcode: (b) (6)

Dr. Tabak as Leader: (b) (6)

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
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(b) (6); (b) (6); (b) (6); (b) (6)
(b) (6); (b) (6); (b) (6); Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6); Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7adfcdb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6); (b) (6); (b) (6); Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras];
(b) (6); Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6)
Subject: RE: ACTIV Preclinical working group (Friday meeting)

Attachments: PRECLINICAL_Working Group_Agenda_0520_d1.pptx; ACTIV PRECLINICAL_Animal Model Inventory_20200514
jpm.xlsx

Hi all,

Please find attached some materials to aid in our discussion today. The first document contains the agenda as well as our WG's objectives and timeline. Also attached is the Animal Model Inventory.

Please let us know if you have any questions.

Best,

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] <(b) (6)>
Sent: Tuesday, April 14, 2020 6:49 PM
To: Menetski, Joseph (FNIH) [T]; (b) (6); (b) (6); (b) (6); (b) (6); (b) (6);
(b) (6); (b) (6); Baric, Ralph; (b) (6); Ottinger, Elizabeth
(NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon
(FDA/CDER); (b) (6); (b) (6); (b) (6); Parker, Ashley (NIH/OD)
[E]; Collins, Francis (NIH/OD) [E]; (b) (6); Adams, Peter (OS/ASPR/BARDA)
Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T];
Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI);
Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH)
[T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan;
Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson,
Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E];
Rodriguez, Robin D; Dave Frankowski
Subject: ACTIV Preclinical working group (Friday meeting)
When: Friday, May 22, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://zoom.us/>; (b) (6)

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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Eron, Joseph J Jr [(b) (6) Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]
Subject: ACTIV TX-Clinical Master Protocol Subgroup #15
Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_11May2020 Meeting Guide.pdf; Adapt Out COVID Overview051120.pdf
Location: https://fnih.zoom. (b) (6)

Start: 5/11/2020 5:00:00 PM
End: 5/11/2020 6:30:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Smith, David; Kim, Peter (NIH/NIAID) [E]; (b) (6) Eron, Joe; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters, Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Eron, Joseph J Jr; Javan, Arzhang (NIH/NIAID) [E]

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for today's call. We will be discussing the statistical simulations the group has put together for ACTT-3, as well as we will have a presentation from the ACTG group on their outpatient master protocol.

Thanks,
Stacey

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Subject: Re: Master Protocol Development and Agent Prioritization Manuscripts for ACTIV TX-Clinical Comment

Hi Stacey

Manuscript reads well and is in excellent shape. I have no further comments.

Best regards

John

On Thu, Jan 21, 2021 at 4:57 AM Adam, Stacey (FNIH) [T] < (b) (6) > wrote:

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Dear ACTIV TX-Clinical WG,

As discussed on last week's call, I am now distributing the current 90% finalized drafts of the Master Protocol Development and Agent Prioritization manuscripts for this group's review and comment. Please find the manuscripts at these links:

Agent Prioritization:

https://docs.google.com/document/d/1w_wKs1_bX2E_pdfmcXvz-0qW2cMey0w0RqUu1wMU2vE/edit

APAR0000017573-2517831

Master Protocol Development:

https://docs.google.com/document/d/1nIZT4_rPR6v1lbtCEdnE2hUumo6BsiQu85dW7Pd0xGU/edit

We would ask that the team members here review the document to ensure that you feel it accurately reflects the process and efforts of this WG. *We would ask that the group focus on any major comments that you feel are “critical” to the manuscript. We would ask that you not wordsmith or refine for style at this point, as each of these documents have been through about ~10 of your colleagues for drafting, review, and refinement.*

If you do have suggestions, please follow the instructions at the top of the Google document in green to turn on suggestions in the document before you edit. **If you do choose to comment, please ensure that you have all suggestions returned by a week from today on Wednesday, January 27th at 5pm ET.**

Finally, we would ask that you do not share these manuscripts with anyone outside of this distribution list at this time. They are still in draft phase and confidential, so we do not wish to hurt our chance of publication by having them made public too early and in their unfinished form.

Thank you in advance for your assistance with this effort.

Kind regards,

Stacey

Stacey J. Adam, PhD

Director, Cancer

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CC: Demarcus [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)]; Elizabeth Kim [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [(b) (6)]; Eron, Joseph J Jr [(b) (6)]; Smith, David [(b) (6)]; Paul Klekotka [(b) (6)]; Ajay Nirula [(b) (6)]; Elsaid, Olivia [(b) (6)]; Robert Jan Benschoep [(b) (6)]; Lei Shen [(b) (6)]; Chen, Helen Q. [(b) (6)]
Subject: Notes from the ACTIV TX-Clinical mAb Outpatient WT Meeting-3
Attachments: ACTIV_Therapeutics-Clinical_ACTIV TX-Clinical mAb Outpatient WT Meeting-3_20May2020_Key Takeaways.pdf; Statistical Considerations - Proschan.docx

Dear ACTIV TX-Clinical mAb Outpatient WT,

Please find the notes from last night's writing team meeting for the group's reference. Please note the action items for follow up and the bolded text actions and decisions.

In addition, as requested, I am circulated the document of Statistical Considerations that Mike Proschan put together for ACTIV-1, the large Phase 3.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
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Sent: 4/22/2020 1:36:18 AM
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CC: Elizabeth Kim [(b) (6)] Menetski, Joseph (FNIH) [T] [(b) (6)]; Alvarez, Rosa Maria [(b) (6)] Salathin, Carla [(b) (6)] [(b) (6)] [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [(b) (6)] Melencio, Cheryl (FNIH) [T] [(b) (6)] Lucas Smalldon [(b) (6)] Walker, Paula (NIH/NINDS) [E] [(b) (6)]; Ward, Jackie (NIH/NINDS) [E] [(b) (6)]
Subject: ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5 (Materials)
Attachments: 2020-04-28_TX_Clinical_WG_Agent_Prioritization_Sub-WG_Summary.pdf; ACTIV Therapeutics Clinical_Agent Prioritization Sub-Group Meeting Agenda_04302020.pdf
Location: <https://fnih.zoom.us/> [(b) (6)]
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End: 4/30/2020 8:00:00 PM
Show Time As: Busy

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; [(b) (6)] [(b) (6)] Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] [(b) (6)]

Dear TX-Clinical Agent Prioritization Subgroup,

Thank you all for all the hard work you all are doing right now for the agent scoring. I appreciate all the information sharing that has been happening today to allow others to see the compound information you have found. I look forward chatting with you tomorrow to address any questions you may need addressed before our discussion of the results on Friday.

For reference tomorrow, please find attached the summary from yesterday's meeting and the agenda for tomorrow's meeting.

Thanks,

Stacey

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Sent: 7/21/2020 7:19:30 PM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Bancel, Stephane [(b) (6) Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6)]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6) Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Erck, Stan [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John [(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh [(b) (6) Pangalos, Mene [(b) (6) Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaafe06ebd70-parkeras]; Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Rasi, Guido [(b) (6) Reed, John [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [(b) (6) Tsai, John [(b) (6) Vessey, Rupert [(b) (6) m]; Virgin, Skip [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy

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[(b) (6) Lever, Susan [(b) (6) McManus, Ayanna (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Minnich, Beth
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 [(b) (6) Riccobene, Kim [(b) (6) Riffin, Mary [(b) (6)
 Ripley, Nadege [(b) (6) Suhana, Tina (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fbb3e468057-esuhana];
 Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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End: 8/26/2020 8:30:00 PM

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Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]

Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hardesty, Rebecca (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riffin, Mary; Ripley, Nadege; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]

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